HSS S2S REST Web Service Technical User Guide

HSS S2S REST Web Service Technical User Guide

Document Version 1.0.0
Oct 25, 2024

Document History

Date	HSS Version	Document Version	Description of Change	Author
25 Oct 2024	1.0	1.0.0	Initial release of REST webservice user guide	Grmahun T

1. General Information

1.1 Purpose

The purpose of this document is to provide a general description and usage guide for the Human Subjects System (HSS) External REST Web Service for Institutes/Centers (ICs).

1.2 General Description

The HSS External REST web service is available for the ICs to retrieve/submit human subjects studies data from/to the HSS database.

The REST web service endpoints primarily support **XML-based requests and responses**, adhering to the defined XML schema for structured data exchange. However, for the **SubmitPdfAttachment** Service, it accepts requests in **multipart/form-data** format, allowing for the submission of PDF file attachment alongside other request data. This format ensures interoperability across different systems that use XML and PDF attachments for structured data exchange.

1.3 Security

The system that calls the HSS External REST web service must pass credentials for a system account. For more information on system accounts, please refer to the Manage System Accounts mini user guide. The system accounts should have the following role for the ICs of the applications for which the data will be retrieved.

Roles to be used by the IC users

Role Name	Description	Role Context

HSCT_S2S_SERVICE_IC_R EAD_ROLE	Role for retrieving study data; this role is for grants and contracts only	AGENCY_ IC
HSCT_S2S_IC_UPDATE_RO LE	Role for inserting , updating study data for submitExternalData and submitPdfAttachmentForm. This role is for grants and contracts studies	AGENCY_ IC
ACCESS_DOC_UPLD_SERV _IC_HSCTA	Role to upload clinical trial document; this is needed for upload attachments in eRA Document Service. This role is for grants and contracts studies	AGENCY_ IC
HSCT_S2S_INTRAMURAL_ READ_ROLE	Role for retrieving study data ; this role is for Intramural grants.	AGENCY
HSCT_S2S_INTRAMURAL_ UPD_ROLE	Role for inserting , updating study data for submitExternalData ; this role is for Intramural grants.	AGENCY

1.4 Prerequisites

Institutes/Centers (ICs) need certificate-based authentication to access the HSS ExternalService REST web service. For instructions on configuring the certificate, please refer to the Internal S2S Guide for eRA Web Services. As indicated in Section 3 of the Internal S2S Guide for eRA Web Services, the certificate needs to be registered after it has been procured. This step is conducted by the IC Coordinator.

1.5 Service Locations for ICs

Following are the end point URL's for the web service for ICs for each eRA environments.

Environment	URL
TEST	https://services.internal.test.era.nih.gov/hsct/api
STAGE	https://services.internal.stage.era.nih.gov/hsct/api
PROD	https://services.internal.era.nih.gov/hsct/api

2. HSS ExternalService Retrieval Service

2.1 Approach

When the study information is needed for an application, the caller will provide eRA Application ID. The service will find the competitive segment application ID for the input application ID. It will then return the list of regular studies where the segment is primary, delayed-onset studies where the segment is primary, and the list of all studies where the segment has "associated" relationship. The service will return the list of subprojects who don't have any studies for grants.

Studies may have multiple attachments. The service will return the HREF for each attachment. The caller will have to call eRA Document Service to retrieve those attachments. See section 5.1 for details.
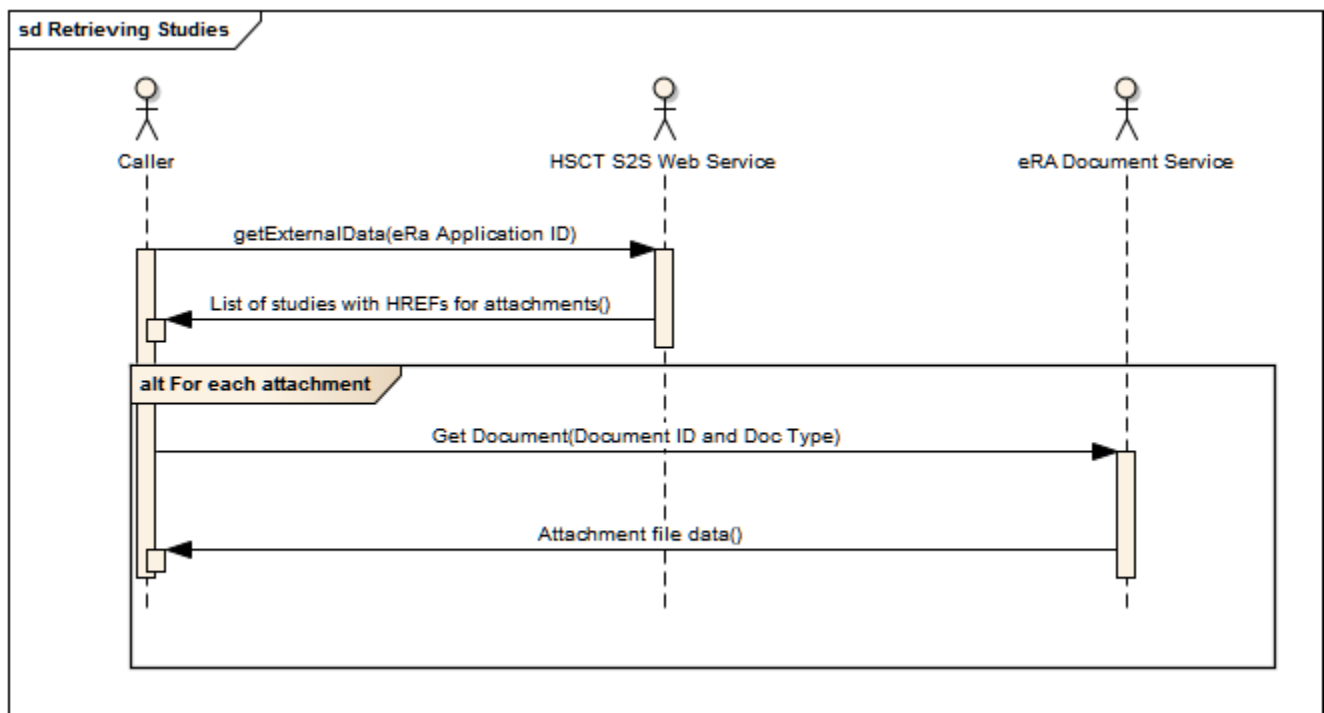
2.2 Get HSS Study data - getExternalData

The name of the method to retrieve the study data is "getExternalData".

Web Attributes	Details
Endpoint	/getExternalData
Method	POST
Path Params	**NA**
Request Media Type	application/xml

Request Payload	```xml
	<hsc:GetExternalDataRequest applId="11160452" xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService"/>
	``

Success Response	Http Status: **200 Ok**
	
	Example :
	
	Response
	
	``xml
	<GetExternalDataResponse xmlns="http://era.nih.gov/hsct/HsctExternalService" xmlns:ns2="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0" xmlns:ns3="http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns4="http://apply.grants.gov/system/Global-V1.0" xmlns:ns5="http://era.nih.gov/hsct/HsctStudy-V3.0" xmlns:ns6="http://era.nih.gov/hsct/HsctDelayedOnsetStudy-V1.0">
	    <eraApplicationId>11160452</eraApplicationId>
	    <regularStudies>
	        <ns5:HsctStudy>
	            <ns2:HumanSubjectStudy_3_0 ns2:FormVersion="3.0">
	                <ns2:Study_id>421791</ns2:Study_id>
	``

```xml
            <ns2:StudyTitle>Immune Therapeutics Based on Mechanisms of Inter-Metastatic Diversity
in Small Cell Lung Cancer</ns2:StudyTitle>
            <ns2:ExemptFedReg>N: No</ns2:ExemptFedReg>
            <ns2:ClinicalTrialQuestionnaire>
                <ns2:HumanSubjectsIndicator>Y: Yes</ns2:HumanSubjectsIndicator>
                <ns2:InterventionAssigned>N: No</ns2:InterventionAssigned>
                <ns2:EvaluateIntervention>N: No</ns2:EvaluateIntervention>
                <ns2:HealthRelatedOutcome>N: No</ns2:HealthRelatedOutcome>
            </ns2:ClinicalTrialQuestionnaire>
            <ns2:StudyPopulationCharacteristics>
                <ns2:StudyConditions>small cell lung cancer</ns2:StudyConditions>
                <ns2:EligibilityCriteria>Known small cell lung cancer in an individual capable of
giving informed consent for autopsy. Patients with known small cell lung cancer are defined as
those men or women (aged 18 years of age and over) with one or both of the following: a tissue
biopsy positive for advanced stage (unresectable) or metastatic cancer and/or a radiographic study
consistent with advanced stage (unresectable) and/or metastatic cancer.</ns2:EligibilityCriteria>
                <ns2:AgeLimits>
                    <ns2:MinimumAge>
                        <ns2:Age>18</ns2:Age>
                        <ns2:AgeType>Years</ns2:AgeType>
                    </ns2:MinimumAge>
                    <ns2:MaximumAge>
                        <ns2:AgeType>N/A (No limit)</ns2:AgeType>
                    </ns2:MaximumAge>
                </ns2:AgeLimits>
                <ns2:InclusionOfIndividualsAcrossLifespan>
                    <ns2:attFile>
                        <ns3:FileName>Lifespan_Inclusion.pdf</ns3:FileName>
                        <ns3:MimeType>application/pdf</ns3:MimeType>
                        <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document
/keyId/1268868/HSCTA"/>
                        <ns4:HashValue ns4:hashAlgorithm="SHA-1">McAxyA1XhNh/rYCNwaISp6m3MJY=</ns4:
HashValue>
                    </ns2:attFile>
                </ns2:InclusionOfIndividualsAcrossLifespan>
                <ns2:InclusionOfWomenAndMinorities>
                    <ns2:attFile>
                        <ns3:FileName>Women_+_Minorities_Inclusion.pdf</ns3:FileName>
                        <ns3:MimeType>application/pdf</ns3:MimeType>
                        <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document
/keyId/1268866/HSCTA"/>
                        <ns4:HashValue ns4:hashAlgorithm="SHA-1">7LlWoJdmODnTr7JR7ZHQKLape18=</ns4:
HashValue>
                    </ns2:attFile>
                </ns2:InclusionOfWomenAndMinorities>
                <ns2:RecruitmentAndRetentionPlan>
                    <ns2:attFile>
                        <ns3:FileName>Recruit_+_Retention.pdf</ns3:FileName>
                        <ns3:MimeType>application/pdf</ns3:MimeType>
                        <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document
/keyId/1268867/HSCTA"/>
                        <ns4:HashValue ns4:hashAlgorithm="SHA-1">YOQExUuEjYc1HWJMEJOXrIhNKtk=</ns4:
HashValue>
                    </ns2:attFile>
                </ns2:RecruitmentAndRetentionPlan>
                <ns2:RecruitmentStatus>Completed</ns2:RecruitmentStatus>
                <ns2:FirstSubjectEnrollment>
                    <ns2:EnrollmentDate>2015-07-01</ns2:EnrollmentDate>
                    <ns2:AnticipatedActual>Actual</ns2:AnticipatedActual>
                </ns2:FirstSubjectEnrollment>
                <ns2:InclusionEnrollmentReport>
                    <ns2:IER_id>430891</ns2:IER_id>
                    <ns2:InclusionEnrollmentReportTitle>Immune Therapeutics Based on Mechanisms of
Diversity in Small Cell Lung Cancer</ns2:InclusionEnrollmentReportTitle>
                    <ns2:ExistingDatasetOrResource>N: No</ns2:ExistingDatasetOrResource>
                    <ns2:EnrollmentLocationType>Domestic</ns2:EnrollmentLocationType>
                    <ns2:EnrollmentCountry>USA: UNITED STATES</ns2:EnrollmentCountry>
                    <ns2:EnrollmentLocations>Durham, NC</ns2:EnrollmentLocations>
                    <ns2:Comments>We opened an exempted protocol to collect de-identified pleural
effusions from patients with SCLC at Duke U.(Pro00114602; 1 sample collected so far), after all
the propsoed analyses were performed using samples from the IRB protocol originally opened at
```

Moffitt Cancer Center (all 10 patients).
Note the change in the title and declaration of exemption. No more samples will be collected at
Moffitt.</ns2:Comments>

```xml
                <ns2:Planned>
                    <ns2:NotHispanic>
                        <ns2:Female>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>1</ns2:Black>
                            <ns2:White>1</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:Total>2</ns2:Total>
                        </ns2:Female>
                        <ns2:Male>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>1</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>1</ns2:Black>
                            <ns2:White>2</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:Total>4</ns2:Total>
                        </ns2:Male>
                    </ns2:NotHispanic>
                    <ns2:Hispanic>
                        <ns2:Female>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>0</ns2:Black>
                            <ns2:White>0</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:Total>0</ns2:Total>
                        </ns2:Female>
                        <ns2:Male>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>1</ns2:Black>
                            <ns2:White>2</ns2:White>
                            <ns2:MultipleRace>1</ns2:MultipleRace>
                            <ns2:Total>4</ns2:Total>
                        </ns2:Male>
                    </ns2:Hispanic>
                    <ns2:Total>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>1</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>3</ns2:Black>
                        <ns2:White>5</ns2:White>
                        <ns2:MultipleRace>1</ns2:MultipleRace>
                        <ns2:Total>10</ns2:Total>
                    </ns2:Total>
                </ns2:Planned>
                <ns2:Cumulative>
                    <ns2:NotHispanic>
                        <ns2:Female>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>0</ns2:Black>
                            <ns2:White>0</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:UnknownRace>0</ns2:UnknownRace>
                            <ns2:Total>0</ns2:Total>
                        </ns2:Female>
                        <ns2:Male>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>0</ns2:Black>
```

```xml
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:Male>
                    <ns2:UnknownGender>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:UnknownGender>
                </ns2:NotHispanic>
                <ns2:Hispanic>
                    <ns2:Female>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:Female>
                    <ns2:Male>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:Male>
                    <ns2:UnknownGender>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:UnknownGender>
                </ns2:Hispanic>
                <ns2:UnknownEthnicity>
                    <ns2:Female>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>2</ns2:UnknownRace>
                        <ns2:Total>2</ns2:Total>
                    </ns2:Female>
                    <ns2:Male>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>8</ns2:UnknownRace>
                        <ns2:Total>8</ns2:Total>
                    </ns2:Male>
                    <ns2:UnknownGender>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
```

```xml
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>0</ns2:Black>
                            <ns2:White>0</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:UnknownRace>0</ns2:UnknownRace>
                            <ns2:Total>0</ns2:Total>
                        </ns2:UnknownGender>
                    </ns2:UnknownEthnicity>
                    <ns2:Total>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>10</ns2:UnknownRace>
                        <ns2:Total>10</ns2:Total>
                    </ns2:Total>
                </ns2:Cumulative>
            </ns2:InclusionEnrollmentReport>
            <ns2:InclusionEnrollmentReport>
                <ns2:IER_id>531336</ns2:IER_id>
                <ns2:InclusionEnrollmentReportTitle>MCC 17820, Establishing and Maintaining a
Rapid Tissue Donation Program (Pro00014653)</ns2:InclusionEnrollmentReportTitle>
                <ns2:ExistingDatasetOrResource>Y: Yes</ns2:ExistingDatasetOrResource>
                <ns2:EnrollmentLocationType>Domestic</ns2:EnrollmentLocationType>
                <ns2:EnrollmentCountry>USA: UNITED STATES</ns2:EnrollmentCountry>
                <ns2:EnrollmentLocations>Moffitt cancer center</ns2:EnrollmentLocations>
                <ns2:Comments>Patients with SCLC enrolled in a rapid autopsy program at Moffitt
were already analyzed and included in this report.
Pleural effusions from de-identified patients with SCLC prospectively colected at Duke were
declared exempted (not human subjects)</ns2:Comments>
                <ns2:Planned>
                    <ns2:NotHispanic>
                        <ns2:Female>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>1</ns2:Black>
                            <ns2:White>1</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:Total>2</ns2:Total>
                        </ns2:Female>
                        <ns2:Male>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>1</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>1</ns2:Black>
                            <ns2:White>2</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:Total>4</ns2:Total>
                        </ns2:Male>
                    </ns2:NotHispanic>
                    <ns2:Hispanic>
                        <ns2:Female>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>0</ns2:Black>
                            <ns2:White>1</ns2:White>
                            <ns2:MultipleRace>0</ns2:MultipleRace>
                            <ns2:Total>1</ns2:Total>
                        </ns2:Female>
                        <ns2:Male>
                            <ns2:AmericanIndian>0</ns2:AmericanIndian>
                            <ns2:Asian>0</ns2:Asian>
                            <ns2:Hawaiian>0</ns2:Hawaiian>
                            <ns2:Black>1</ns2:Black>
                            <ns2:White>1</ns2:White>
                            <ns2:MultipleRace>1</ns2:MultipleRace>
```

```xml
                    <ns2:Total>3</ns2:Total>
                </ns2:Male>
            </ns2:Hispanic>
            <ns2:Total>
                <ns2:AmericanIndian>0</ns2:AmericanIndian>
                <ns2:Asian>1</ns2:Asian>
                <ns2:Hawaiian>0</ns2:Hawaiian>
                <ns2:Black>3</ns2:Black>
                <ns2:White>5</ns2:White>
                <ns2:MultipleRace>1</ns2:MultipleRace>
                <ns2:Total>10</ns2:Total>
            </ns2:Total>
        </ns2:Planned>
        <ns2:Cumulative>
            <ns2:NotHispanic>
                <ns2:Female>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
                    <ns2:Black>0</ns2:Black>
                    <ns2:White>0</ns2:White>
                    <ns2:MultipleRace>0</ns2:MultipleRace>
                    <ns2:UnknownRace>0</ns2:UnknownRace>
                    <ns2:Total>0</ns2:Total>
                </ns2:Female>
                <ns2:Male>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
                    <ns2:Black>0</ns2:Black>
                    <ns2:White>0</ns2:White>
                    <ns2:MultipleRace>0</ns2:MultipleRace>
                    <ns2:UnknownRace>0</ns2:UnknownRace>
                    <ns2:Total>0</ns2:Total>
                </ns2:Male>
                <ns2:UnknownGender>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
                    <ns2:Black>0</ns2:Black>
                    <ns2:White>0</ns2:White>
                    <ns2:MultipleRace>0</ns2:MultipleRace>
                    <ns2:UnknownRace>0</ns2:UnknownRace>
                    <ns2:Total>0</ns2:Total>
                </ns2:UnknownGender>
            </ns2:NotHispanic>
            <ns2:Hispanic>
                <ns2:Female>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
                    <ns2:Black>0</ns2:Black>
                    <ns2:White>0</ns2:White>
                    <ns2:MultipleRace>0</ns2:MultipleRace>
                    <ns2:UnknownRace>0</ns2:UnknownRace>
                    <ns2:Total>0</ns2:Total>
                </ns2:Female>
                <ns2:Male>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
                    <ns2:Black>0</ns2:Black>
                    <ns2:White>0</ns2:White>
                    <ns2:MultipleRace>0</ns2:MultipleRace>
                    <ns2:UnknownRace>0</ns2:UnknownRace>
                    <ns2:Total>0</ns2:Total>
                </ns2:Male>
                <ns2:UnknownGender>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
```

```xml
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:UnknownGender>
                </ns2:Hispanic>
                <ns2:UnknownEthnicity>
                    <ns2:Female>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>2</ns2:UnknownRace>
                        <ns2:Total>2</ns2:Total>
                    </ns2:Female>
                    <ns2:Male>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>12</ns2:UnknownRace>
                        <ns2:Total>12</ns2:Total>
                    </ns2:Male>
                    <ns2:UnknownGender>
                        <ns2:AmericanIndian>0</ns2:AmericanIndian>
                        <ns2:Asian>0</ns2:Asian>
                        <ns2:Hawaiian>0</ns2:Hawaiian>
                        <ns2:Black>0</ns2:Black>
                        <ns2:White>0</ns2:White>
                        <ns2:MultipleRace>0</ns2:MultipleRace>
                        <ns2:UnknownRace>0</ns2:UnknownRace>
                        <ns2:Total>0</ns2:Total>
                    </ns2:UnknownGender>
                </ns2:UnknownEthnicity>
                <ns2:Total>
                    <ns2:AmericanIndian>0</ns2:AmericanIndian>
                    <ns2:Asian>0</ns2:Asian>
                    <ns2:Hawaiian>0</ns2:Hawaiian>
                    <ns2:Black>0</ns2:Black>
                    <ns2:White>0</ns2:White>
                    <ns2:MultipleRace>0</ns2:MultipleRace>
                    <ns2:UnknownRace>14</ns2:UnknownRace>
                    <ns2:Total>14</ns2:Total>
                </ns2:Total>
            </ns2:Cumulative>
        </ns2:InclusionEnrollmentReport>
    </ns2:StudyPopulationCharacteristics>
    <ns2:ProtectionMonitoringPlans>
        <ns2:ProtectionOfHumanSubjects>
            <ns2:attFile>
                <ns3:FileName>New_Protection_of_Human_Subjects(Exempt).pdf</ns3:FileName>
                <ns3:MimeType>application/pdf</ns3:MimeType>
                <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document
/keyId/1945909/HSCTA"/>
                <ns4:HashValue ns4:hashAlgorithm="SHA-1">m3eZw47u1QL5qYWK+2uNBBAI3Eg=</ns4:
HashValue>
            </ns2:attFile>
        </ns2:ProtectionOfHumanSubjects>
        <ns2:MultiSiteStudy>N: No</ns2:MultiSiteStudy>
        <ns2:DataSafetyMonitoringPlan>
            <ns2:attFile>
                <ns3:FileName>Data_safety_and_monitoring_plan.pdf</ns3:FileName>
                <ns3:MimeType>application/pdf</ns3:MimeType>
                <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document
/keyId/1945910/HSCTA"/>
                <ns4:HashValue ns4:hashAlgorithm="SHA-1">76hgkv3ui2NE+wpexpdlCZzdu3o=</ns4:
```

```xml
HashValue>
                    </ns2:attFile>
                </ns2:DataSafetyMonitoringPlan>
                <ns2:BoardAppointed>N: No</ns2:BoardAppointed>
            </ns2:ProtectionMonitoringPlans>
            <ns2:ProtocolSynopsis>
                <ns2:StudyDesign>
                    <ns2:NIHPhase3ClinicalTrial>N: No</ns2:NIHPhase3ClinicalTrial>
                    <ns2:MaskingType>
                        <ns2:Participant>N: No</ns2:Participant>
                        <ns2:CareProvider>N: No</ns2:CareProvider>
                        <ns2:Investigator>N: No</ns2:Investigator>
                        <ns2:OutcomesAssessor>N: No</ns2:OutcomesAssessor>
                    </ns2:MaskingType>
                </ns2:StudyDesign>
                <ns2:FDARegulatedIntervention>N: No</ns2:FDARegulatedIntervention>
            </ns2:ProtocolSynopsis>
        </ns2:HumanSubjectStudy_3_0>
        <ns5:postSubmissionInfo>
            <ns5:applicableClinicalTrialUnderFdaa>N: No</ns5:applicableClinicalTrialUnderFdaa>
        </ns5:postSubmissionInfo>
        <ns5:ierParticipantData>
            <ns5:ierId>531336</ns5:ierId>
            <ns5:participantDataAttachment>
                <ns3:FileName>ParticipantLevelData.csv</ns3:FileName>
                <ns3:MimeType>text/csv</ns3:MimeType>
                <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document/keyId
/1983704/HSCTA"/>
                <ns4:HashValue ns4:hashAlgorithm="SHA-1">EsAFDNPNVZ7/dy3mI0ds5onsdZ4=</ns4:
HashValue>
            </ns5:participantDataAttachment>
        </ns5:ierParticipantData>
        <ns5:ierParticipantData>
            <ns5:ierId>430891</ns5:ierId>
            <ns5:participantDataAttachment>
                <ns3:FileName>ParticipantLevelDataXDukeXRPPR.csv</ns3:FileName>
                <ns3:MimeType>text/csv</ns3:MimeType>
                <ns3:FileLocation ns3:href="era://document/docservice/dataservices/document/keyId
/1988634/HSCTA"/>
                <ns4:HashValue ns4:hashAlgorithm="SHA-1">+xF9qVjVP7abMvZgVremT5aPDSU=</ns4:
HashValue>
            </ns5:participantDataAttachment>
        </ns5:ierParticipantData>
    </ns5:HsctStudy>
    <commonStudyInfo>
        <studyAttributes>
            <lastSubmissionDate>2024-08-01-04:00</lastSubmissionDate>
            <studyStatus>Accepted</studyStatus>
            <inclusionMonitoringCode>Y</inclusionMonitoringCode>
        </studyAttributes>
    </commonStudyInfo>
  </regularStudies>
</GetExternalDataResponse>
```

Error Response	• Http Status: **403**

```
{
  "code": "403",
  "message": "Service account does not have privileges for this operation."
}
```

• Http Status: **422**

```
{
  "code": "422",
  "message": "Application ID or Admin Org null does not exist."
}
```

• Http Status: **500**

```
{
    "code": "500",
    "message": " Error ID: 1729873538358 Could not unmarshal to [class gov.nih.era.hsct.
hsctexternalservice.auto.ExternalDataRequest]: null; nested exception is javax.xml.bind.
UnmarshalException\n - with linked exception:\n[org.xml.sax.SAXParseException; lineNumber: 1;
columnNumber: 100; cvc-datatype-valid.1.2.1: 'null' is not a valid value for 'integer'.]"
}
```

2.3 Input Values

After successful authentication into HSS ExternalService web service, the following field information applies:

#	Element Name	Description	Rule	Error when rule is not met	Error Code
1	applId	eRA application ID for which the studies need to be retrieved	Required	Http Status Error	N/A

Sample REST XML request:

```
<hsc:GetExternalDataRequest applId="11160452" xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService"/>
```

2.4 Output Values

The Web Service will return the following results:

- Application ID that has been passed as input
- List of regular studies for which the competing segment of the given application ID is primary (regularStudies)
- List of delayed-onset studies for which the competing segment of the given application ID is primary (delayedStudies)
- List of regular and delayed studies for which the competing segment of the given application ID plays a supporting role
- List of subprojects without studies

Output Structure

See section 6.2 for a sample output REST XML response.

#	Element Name	Description	XSD Complex Type Used
1	eraApplicationId	eRA application ID that was sent to the web service as an input.	
2	regularStudies	List of regular study info for the competing segment of the input application ID. Only studies for which the competing segment is the primary will be included here.	ExternalRegularStudyInfo of HsctExternalService.xsd

#	Element Name	Description	XSD Complex Type Used
3	delayedStudies	List of delayed-onset study info for the competing segment of the input application ID. Only studies for which the competing segment is the primary will be included here. See https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#Delayed for information on these fields.	ExternalDelayedStudyInfo of HsctExternalService.xsd
4	associatedRegularStudies	List of regular studies for which the competing segment is secondary will be included here.	ExternalRegularStudyInfo of HsctExternalService.xsd
5	associatedDelayedStudies	List of delayedstudies for which the competing segment is secondary will be included here.	ExternalDelayedStudyInfo of HsctExternalService.xsd
6	subprojectsWithoutStudies	List of subprojects without studies.	ExternalSubProjectInfo of HsctExternalService.xsd

ExternalRegularStudyInfo

#	Element Name	Description	XSD Complex Type Used
1	hsctStudy	It contains human subject study data, post submission information and IER participant data.	HsctStudy of HsctStudy-V3.0.xsd
2	commonStudyInfo	IC subproject ID, subproject application ID and other study attributes.	ExternalCommonStudyInfo of HsctExternalService.xsd

Sample XML for regularStudies (Studies with ierParticipantData available in existing participantData element):

```
<regularStudies>
  <HsctStudy>
    <HumanSubjectStudy_3_0 FormVersion="3.0">
      <StudyTitle>Study Title</StudyTitle>
      <ExemptFedReg>Y: Yes</ExemptFedReg>
      <ClinicalTrialQuestionnaire>
        <HumanSubjectsIndicator>Y: Yes</HumanSubjectsIndicator>
        <InterventionAssigned>Y: Yes</InterventionAssigned>
        <EvaluateIntervention>Y: Yes</EvaluateIntervention>
        <HealthRelatedOutcome>Y: Yes</HealthRelatedOutcome>
      </ClinicalTrialQuestionnaire>
    </HumanSubjectStudy_3_0>
    <postSubmissionInfo/>
    <ierParticipantData>
      <ierId>0</ierId>
      <participantData>
        <race>AmericanIndian</race>
        <ethnicity>Hispanic</ethnicity>
        <gender>Male</gender>
        <ageType>Years</ageType>
      </participantData>
    </ierParticipantData>
    <sourceUniqueValue>sourceUniqueValue</sourceUniqueValue>
  </HsctStudy>
  <commonStudyInfo>
    <subProjectInfo>
      <icSubprojectId>1234</icSubprojectId>
      <subprojectApplId>123434872</subprojectApplId>
      <projectTitle>Project Title</projectTitle>
    </subProjectInfo>
    <studyAttributes>
      <lastSubmissionDate>2019-01-18</lastSubmissionDate>
            <reportingProject>R01HL018292-19</reportingProject>
      <studyStatus>Receivd By Agency</studyStatus>
      <inclusionMonitoringCode>Y</inclusionMonitoringCode>
    </studyAttributes>
    <sourceUniqueValue>SUV_1001</sourceUniqueValue>
  </commonStudyInfo>
</regularStudies>
```

Sample XML for regularStudies (Studies with ierParticipantData submitted in new element participantDataAttachment):

```xml
<regularStudies>
  <HsctStudy>
    <HumanSubjectStudy_3_0 FormVersion="3.0">
      <StudyTitle>Study Title</StudyTitle>
      <ExemptFedReg>Y: Yes</ExemptFedReg>
      <ClinicalTrialQuestionnaire>
        <HumanSubjectsIndicator>Y: Yes</HumanSubjectsIndicator>
        <InterventionAssigned>Y: Yes</InterventionAssigned>
        <EvaluateIntervention>Y: Yes</EvaluateIntervention>
        <HealthRelatedOutcome>Y: Yes</HealthRelatedOutcome>
      </ClinicalTrialQuestionnaire>
    </HumanSubjectStudy_3_0>
    <postSubmissionInfo/>
    <ierParticipantData>
      <ierId>0</ierId>
            <participantDataAttachment>
                    <FileName>ParticipantLevelData-Template.csv</FileName>
                    <MimeType>text/csv</MimeType>
                    <FileLocation href="era://document/docservice/dataservices/document/keyId/41507785
/HSCTA"/>
                    <HashValue hashAlgorithm="SHA-1">BAQOue13GPEeIyT+n6A4fEBV5FY=</HashValue>
            </participantDataAttachment>
     </ierParticipantData>
    <sourceUniqueValue>sourceUniqueValue</sourceUniqueValue>
  </HsctStudy>
  <commonStudyInfo>
    <subProjectInfo>
      <icSubprojectId>1234</icSubprojectId>
      <subprojectApplId>123434872</subprojectApplId>
      <projectTitle>Project Title</projectTitle>
    </subProjectInfo>
    <studyAttributes>
      <lastSubmissionDate>2019-01-18</lastSubmissionDate>
            <reportingProject>R01HL018292-19</reportingProject>
      <studyStatus>Receivd By Agency</studyStatus>
      <inclusionMonitoringCode>Y</inclusionMonitoringCode>
    </studyAttributes>
    <sourceUniqueValue>SUV_1001</sourceUniqueValue>
  </commonStudyInfo>
</regularStudies>
```

ExternalDelayedStudyInfo

#	Element Name	Description	XSD Complex Type Used
1	delayedStudy	It contains the study title, anticipated clinical trial flag and justification.	HsctDelayedOnsetStudy of HsctDelayedOnsetStudy.xsd
2	commonStudyInfo	IC subproject ID, subproject application ID and other study attributes.	ExternalCommonStudyInfo of HsctExternalService.xsd

Sample XML for delayedStudies:

```
    <delayedStudies>
     <HsctDelayedOnsetStudy>
       <studyId>0</studyId>
       <studyTitle>studyTitle</studyTitle>
       <anticipatedClinicalTrial>Y: Yes</anticipatedClinicalTrial>
       <sourceUniqueValue>sourceUniqueValue</sourceUniqueValue>
       <justification>
         <attFile>
           <att:FileName>att:FileName</att:FileName>
           <att:MimeType>att:MimeType</att:MimeType>
           <att:FileLocation att:href="http://tempuri.org"/>
           <glob:HashValue glob:hashAlgorithm="">MA==</glob:HashValue>
         </attFile>
       </justification>
     </HsctDelayedOnsetStudy>
     <commonStudyInfo>
       <subProjectInfo>
         <icSubprojectId>1235</icSubprojectId>
         <subprojectApplId>1233456872</subprojectApplId>
       </subProjectInfo>
       <studyAttributes>
         <lastSubmissionDate>2017-01-20</lastSubmissionDate>
         <reportingProject>R01HL018292-19</reportingProject>
         <studyStatus>Received by Agency</studyStatus>
         <inclusionMonitoringCode>Y</inclusionMonitoringCode>
       </studyAttributes>
       <sourceUniqueValue>SUV_1001</sourceUniqueValue>
     </commonStudyInfo>
    </delayedStudies>
```

ExternalCommonStudyInfo

#	Element Name	Description	XSD Complex Type Used
1	subProjectInfo	Subproject attributes like IC Subproject ID and subproject application Id.	ExternalSubprojectInfo of HsctExternalService.xsd
2	studyAttributes	Attributes of study like submission date, reporting project etc.	ExternalStudyAttributes of HsctExternalService.xsd
3	sourceUniqueValue	Unique study ID given by the external systems	

ExternalSubprojectInfo

#	Element Name	Description
1	icSubprojectId	IC Subproject ID if the associated project is a subproject Null otherwise.
2	subprojectApplId	eRA application ID of the subproject if the associated project is a subproject . Null otherwise.

ExternalStudyAttributes

#	Element Name	Description
1	lastSubmissionDate	Last submission Date
2	reportingProject	Reporting Project
3	studyStatus	Study Status. Valid values: Received by Agency Accepted

4	inclusionMonitoringCode	Inclusion monitoring code. Valid Values: Y/N

HsctStudy

#	Element Name	Description	XSD Complex Type Used
1	HumanSubjectStudy_3_0	HumanSubjectStudy_3_0 type data from grants.gov schema https://apply07.grants.gov/apply/forms/schemas/HumanSubjectStudy_3_0-V3.0.xsd See https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#StudyRecord for more information on these fields.	HumanSubjectStudy_3_0 of HumanSubjectStudy_3_0-V3.0.xsd
2	postSubmissionInfo	Post submission study information	PostSubmissionInfoType of HsctStudy-V3.0.xsd
3	ierParticipantData	List of participant data. List elements are of type IerParticipantDataType.	IerParticipantDataType of HsctStudy-V3.0.xsd

Sample XML for HumanSubjectStudy:

```
<ns4:HsctStudy xmlns:ns1="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0" xmlns:ns2="http://apply.
grants.gov/system/Attachments-V1.0" xmlns:ns3="http://apply.grants.gov/system/Global-V1.0" xmlns:ns4="
http://era.nih.gov/hsct/HsctStudy-V3.0">
    <ns1:HumanSubjectStudy_3_0 ns1:FormVersion="3.0">
        <ns1:Study_id>772396</ns1:Study_id>
        <ns1:StudyTitle>Stressors and Cardio-Metabolic Disease in Police: A 12-year Longitudinal Study</ns1:
StudyTitle>
        <ns1:ExemptFedReg>N: No</ns1:ExemptFedReg>
        <ns1:ExemptionNumbers>
            <ns1:ExemptionNumber>E2</ns1:ExemptionNumber>
            <ns1:ExemptionNumber>E3</ns1:ExemptionNumber>
        </ns1:ExemptionNumbers>
        <ns1:ClinicalTrialQuestionnaire>
            <ns1:HumanSubjectsIndicator>Y: Yes</ns1:HumanSubjectsIndicator>
            <ns1:InterventionAssigned>N: No</ns1:InterventionAssigned>
            <ns1:EvaluateIntervention>N: No</ns1:EvaluateIntervention>
            <ns1:HealthRelatedOutcome>N: No</ns1:HealthRelatedOutcome>
        </ns1:ClinicalTrialQuestionnaire>
        <ns1:ClinicalTrialsIdentifier>NCT04230824</ns1:ClinicalTrialsIdentifier>
        <ns1:StudyPopulationCharacteristics>
            <ns1:StudyConditions>Pharmacological Treatments for Obstructive Sleep Apnea</ns1:StudyConditions>
            <ns1:EligibilityCriteria>Inclusion criteria claustrophobia.</ns1:EligibilityCriteria>
            <ns1:AgeLimits>
                <ns1:MinimumAge>
                    <ns1:Age>21</ns1:Age>
                    <ns1:AgeType>Years</ns1:AgeType>
                </ns1:MinimumAge>
                <ns1:MaximumAge>
                    <ns1:Age>70</ns1:Age>
                    <ns1:AgeType>Years</ns1:AgeType>
                </ns1:MaximumAge>
            </ns1:AgeLimits>
            <ns1:InclusionOfIndividualsAcrossLifespan>
                <ns1:attFile>
                    <ns2:FileName>ASSIST_CT_InclnIndvAcrsLf_2.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/2757050/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWyG+yOj3Reiq0=</ns3:HashValue>
                </ns1:attFile>
            </ns1:InclusionOfIndividualsAcrossLifespan>
            <ns1:InclusionOfWomenAndMinorities>
                <ns1:attFile>
                    <ns2:FileName>Inclusion__(Aim_3)_aw_-.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5095960/HSCTA"
```

```
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">v2MvcRVF/4bCPX8kGJ4UrsSbGjI=</ns3:HashValue>
                </ns1:attFile>
            </ns1:InclusionOfWomenAndMinorities>
            <ns1:RecruitmentAndRetentionPlan>
                <ns1:attFile>
                    <ns2:FileName>Recruitment_and_Retention_Plan_(Aim_3)_aw.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5095971/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">DETDaMI+gwylWH2Ss2UjiVxy8HI=</ns3:HashValue>
                </ns1:attFile>
            </ns1:RecruitmentAndRetentionPlan>
            <ns1:RecruitmentStatus>Recruiting</ns1:RecruitmentStatus>
            <ns1:StudyTimeline>
                <ns1:attFile>
                    <ns2:FileName>Study_Timeline_For_All_3_Studies_Aim_3.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5095982/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">AUIA7fXtwDLrgqGvsLbyduKKlQE=</ns3:HashValue>
                </ns1:attFile>
            </ns1:StudyTimeline>
            <ns1:FirstSubjectEnrollment>
                <ns1:EnrollmentDate>2024-01-01</ns1:EnrollmentDate>
                <ns1:AnticipatedActual>Anticipated</ns1:AnticipatedActual>
            </ns1:FirstSubjectEnrollment>
            <ns1:InclusionEnrollmentReport>
                <ns1:IER_id>12345678</ns1:IER_id>
                <ns1:InclusionEnrollmentReportTitle>IER Title Study</ns1:InclusionEnrollmentReportTitle>
                <ns1:ExistingDatasetOrResource>N: No</ns1:ExistingDatasetOrResource>
                <ns1:EnrollmentLocationType>Domestic</ns1:EnrollmentLocationType>
                <ns1:EnrollmentCountry>USA: UNITED STATES</ns1:EnrollmentCountry>
                <ns1:EnrollmentLocations>Jersey Hospital</ns1:EnrollmentLocations>
                <ns1:Comments>Temp Comment</ns1:Comments>
                <ns1:Planned>
                    <ns1:NotHispanic>
                        <ns1:Female>
                            <ns1:AmericanIndian>0</ns1:AmericanIndian>
                            <ns1:Asian>0</ns1:Asian>
                            <ns1:Hawaiian>0</ns1:Hawaiian>
                            <ns1:Black>19</ns1:Black>
                            <ns1:White>49</ns1:White>
                            <ns1:MultipleRace>0</ns1:MultipleRace>
                            <ns1:Total>68</ns1:Total>
                        </ns1:Female>
                        <ns1:Male>
                            <ns1:AmericanIndian>0</ns1:AmericanIndian>
                            <ns1:Asian>0</ns1:Asian>
                            <ns1:Hawaiian>0</ns1:Hawaiian>
                            <ns1:Black>24</ns1:Black>
                            <ns1:White>129</ns1:White>
                            <ns1:MultipleRace>0</ns1:MultipleRace>
                            <ns1:Total>153</ns1:Total>
                        </ns1:Male>
                    </ns1:NotHispanic>
                    <ns1:Hispanic>
                        <ns1:Female>
                            <ns1:AmericanIndian>0</ns1:AmericanIndian>
                            <ns1:Asian>0</ns1:Asian>
                            <ns1:Hawaiian>0</ns1:Hawaiian>
                            <ns1:Black>0</ns1:Black>
                            <ns1:White>2</ns1:White>
                            <ns1:MultipleRace>0</ns1:MultipleRace>
                            <ns1:Total>2</ns1:Total>
                        </ns1:Female>
                        <ns1:Male>
                            <ns1:AmericanIndian>0</ns1:AmericanIndian>
                            <ns1:Asian>0</ns1:Asian>
                            <ns1:Hawaiian>0</ns1:Hawaiian>
                            <ns1:Black>0</ns1:Black>
```

```xml
                    <ns1:White>17</ns1:White>
                    <ns1:MultipleRace>0</ns1:MultipleRace>
                    <ns1:Total>17</ns1:Total>
                </ns1:Male>
            </ns1:Hispanic>
            <ns1:Total>
                <ns1:AmericanIndian>0</ns1:AmericanIndian>
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>43</ns1:Black>
                <ns1:White>197</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:Total>240</ns1:Total>
            </ns1:Total>
        </ns1:Planned>
        <ns1:Cumulative>
            <ns1:NotHispanic>
                <ns1:Female>
                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
                    <ns1:Asian>0</ns1:Asian>
                    <ns1:Hawaiian>0</ns1:Hawaiian>
                    <ns1:Black>0</ns1:Black>
                    <ns1:White>0</ns1:White>
                    <ns1:MultipleRace>0</ns1:MultipleRace>
                    <ns1:UnknownRace>0</ns1:UnknownRace>
                    <ns1:Total>0</ns1:Total>
                </ns1:Female>
                <ns1:Male>
                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
                    <ns1:Asian>0</ns1:Asian>
                    <ns1:Hawaiian>0</ns1:Hawaiian>
                    <ns1:Black>0</ns1:Black>
                    <ns1:White>0</ns1:White>
                    <ns1:MultipleRace>0</ns1:MultipleRace>
                    <ns1:UnknownRace>0</ns1:UnknownRace>
                    <ns1:Total>0</ns1:Total>
                </ns1:Male>
                <ns1:UnknownGender>
                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
                    <ns1:Asian>0</ns1:Asian>
                    <ns1:Hawaiian>0</ns1:Hawaiian>
                    <ns1:Black>0</ns1:Black>
                    <ns1:White>0</ns1:White>
                    <ns1:MultipleRace>0</ns1:MultipleRace>
                    <ns1:UnknownRace>0</ns1:UnknownRace>
                    <ns1:Total>0</ns1:Total>
                </ns1:UnknownGender>
            </ns1:NotHispanic>
            <ns1:Hispanic>
                <ns1:Female>
                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
                    <ns1:Asian>0</ns1:Asian>
                    <ns1:Hawaiian>0</ns1:Hawaiian>
                    <ns1:Black>0</ns1:Black>
                    <ns1:White>0</ns1:White>
                    <ns1:MultipleRace>0</ns1:MultipleRace>
                    <ns1:UnknownRace>0</ns1:UnknownRace>
                    <ns1:Total>0</ns1:Total>
                </ns1:Female>
                <ns1:Male>
                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
                    <ns1:Asian>0</ns1:Asian>
                    <ns1:Hawaiian>0</ns1:Hawaiian>
                    <ns1:Black>0</ns1:Black>
                    <ns1:White>0</ns1:White>
                    <ns1:MultipleRace>0</ns1:MultipleRace>
                    <ns1:UnknownRace>0</ns1:UnknownRace>
                    <ns1:Total>0</ns1:Total>
                </ns1:Male>
                <ns1:UnknownGender>
                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
```

```xml
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:UnknownRace>0</ns1:UnknownRace>
                <ns1:Total>0</ns1:Total>
            </ns1:UnknownGender>
        </ns1:Hispanic>
        <ns1:UnknownEthnicity>
            <ns1:Female>
                <ns1:AmericanIndian>0</ns1:AmericanIndian>
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:UnknownRace>0</ns1:UnknownRace>
                <ns1:Total>0</ns1:Total>
            </ns1:Female>
            <ns1:Male>
                <ns1:AmericanIndian>0</ns1:AmericanIndian>
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:UnknownRace>0</ns1:UnknownRace>
                <ns1:Total>0</ns1:Total>
            </ns1:Male>
            <ns1:UnknownGender>
                <ns1:AmericanIndian>0</ns1:AmericanIndian>
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:UnknownRace>0</ns1:UnknownRace>
                <ns1:Total>0</ns1:Total>
            </ns1:UnknownGender>
        </ns1:UnknownEthnicity>
        <ns1:Total>
            <ns1:AmericanIndian>0</ns1:AmericanIndian>
            <ns1:Asian>0</ns1:Asian>
            <ns1:Hawaiian>0</ns1:Hawaiian>
            <ns1:Black>0</ns1:Black>
            <ns1:White>0</ns1:White>
            <ns1:MultipleRace>0</ns1:MultipleRace>
            <ns1:UnknownRace>0</ns1:UnknownRace>
            <ns1:Total>0</ns1:Total>
        </ns1:Total>
    </ns1:Cumulative>
    </ns1:InclusionEnrollmentReport>
    </ns1:StudyPopulationCharacteristics>
    <ns1:ProtectionMonitoringPlans>
        <ns1:ProtectionOfHumanSubjects>
            <ns1:attFile>
                <ns2:FileName>Protection_of_Human_Subjects_(Aim_3)_aw.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5095993/HSCTA"
/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">ibgIpvTlZQDVGp8SN4c3gJbIs8=</ns3:HashValue>
            </ns1:attFile>
        </ns1:ProtectionOfHumanSubjects>
        <ns1:MultiSiteStudy>N: No</ns1:MultiSiteStudy>
        <ns1:IRBPlan>
            <ns1:attFile>
                <ns2:FileName>Single_IRB_Plan.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/4987574/HSCTA"
/>
```

```xml
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">VL1nB1gcqfD4G8kjkYkCFWjjTM=</ns3:HashValue>
                </ns1:attFile>
            </ns1:IRBPlan>
            <ns1:DataSafetyMonitoringPlan>
                <ns1:attFile>
                    <ns2:FileName>Data_and_Safety_Monitory_Plan_(Aims_3)_aw.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5096005/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">dW5SjfjJPxXoZIag6oert+TTuI=</ns3:HashValue>
                </ns1:attFile>
            </ns1:DataSafetyMonitoringPlan>
            <ns1:BoardAppointed>N: No</ns1:BoardAppointed>
            <ns1:StudyTeamStructure>
                <ns1:attFile>
                    <ns2:FileName>Overall_Structure_of_the_Study_Team_(Aim_3)_aw.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5096016/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">GO9Le3ghEp6jGa7K0bkMrFjqQY=</ns3:HashValue>
                </ns1:attFile>
            </ns1:StudyTeamStructure>
        </ns1:ProtectionMonitoringPlans>
        <ns1:ProtocolSynopsis>
            <ns1:StudyDesign>
                <ns1:PrimaryPurpose>Dummy Data</ns1:PrimaryPurpose>
                <ns1:Interventions>
                    <ns1:InterventionType>Drug</ns1:InterventionType>
                    <ns1:InterventionName>The drugs have not been chosen yet.</ns1:InterventionName>
                    <ns1:InterventionDescription>atomoxetine 80mg</ns1:InterventionDescription>
                </ns1:Interventions>
                <ns1:Interventions>
                    <ns1:InterventionType>Drug</ns1:InterventionType>
                    <ns1:InterventionName>placebo ssd</ns1:InterventionName>
                    <ns1:InterventionDescription>Placebo 1 night</ns1:InterventionDescription>
                </ns1:Interventions>
                <ns1:StudyPhase>Phase 1/2</ns1:StudyPhase>
                <ns1:NIHPhase3ClinicalTrial>N: No</ns1:NIHPhase3ClinicalTrial>
                <ns1:InterventionModel>Cross-Over</ns1:InterventionModel>
                <ns1:Masking>Y: Yes</ns1:Masking>
                <ns1:MaskingType>
                    <ns1:Participant>Y: Yes</ns1:Participant>
                    <ns1:CareProvider>Y: Yes</ns1:CareProvider>
                    <ns1:Investigator>Y: Yes</ns1:Investigator>
                    <ns1:OutcomesAssessor>Y: Yes</ns1:OutcomesAssessor>
                </ns1:MaskingType>
                <ns1:Allocation>Randomized</ns1:Allocation>
            </ns1:StudyDesign>
            <ns1:OutcomesMeasures>
                <ns1:OutcomeName>Apnea-hypopnea index</ns1:OutcomeName>
                <ns1:OutcomeType>Primary</ns1:OutcomeType>
                <ns1:TimeFrame>baseline and end of each 1 month intervention</ns1:TimeFrame>
                <ns1:OutcomeDescription>Apnea-hypopnea index (events per hour of sleep).</ns1:OutcomeDescription>
            </ns1:OutcomesMeasures>
            <ns1:OutcomesMeasures>
                <ns1:OutcomeName>Nadir oxygen saturation</ns1:OutcomeName>
                <ns1:OutcomeType>Secondary</ns1:OutcomeType>
                <ns1:TimeFrame>baseline and end of each 1 month intervention</ns1:TimeFrame>
                <ns1:OutcomeDescription>Lowest value of overnight oxygen saturation(%).</ns1:OutcomeDescription>
            </ns1:OutcomesMeasures>
            <ns1:OutcomesMeasures>
                <ns1:OutcomeName>Arousal index</ns1:OutcomeName>
                <ns1:OutcomeType>Secondary</ns1:OutcomeType>
                <ns1:TimeFrame>baseline and end of each 1 month intervention</ns1:TimeFrame>
                <ns1:OutcomeDescription>Arousal index (scored per hour of sleep).</ns1:OutcomeDescription>
            </ns1:OutcomesMeasures>
            <ns1:OutcomesMeasures>
                <ns1:OutcomeName>Epworth Sleepiness Scale</ns1:OutcomeName>
                <ns1:OutcomeType>Secondary</ns1:OutcomeType>
                <ns1:TimeFrame>baseline and end of each 1 month intervention</ns1:TimeFrame>
                <ns1:OutcomeDescription>sleepiness</ns1:OutcomeDescription>
```

```xml
            </ns1:OutcomesMeasures>
            <ns1:OutcomesMeasures>
                <ns1:OutcomeName>Functional Outcomes of Sleep Questionnaire</ns1:OutcomeName>
                <ns1:OutcomeType>Secondary</ns1:OutcomeType>
                <ns1:TimeFrame>baseline and end of each 1 month intervention</ns1:TimeFrame>
                <ns1:OutcomeDescription>disease of life</ns1:OutcomeDescription>
            </ns1:OutcomesMeasures>
            <ns1:StatisticalDesignPower>
                <ns1:attFile>
                    <ns2:FileName>Statistical_Design_and_Power_(Aim_3)_aw.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5096027/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">L8CKDYKznGljSPnUocF+27MIIXU=</ns3:HashValue>
                </ns1:attFile>
            </ns1:StatisticalDesignPower>
            <ns1:SubjectParticipationDuration>13 weeks</ns1:SubjectParticipationDuration>
            <ns1:FDARegulatedIntervention>Y: Yes</ns1:FDARegulatedIntervention>
            <ns1:InvestigationalAvailability>
                <ns1:attFile>
                    <ns2:FileName>Availability_of_Investigational_Product_(Aim_3)_aw.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5096038/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">Byf5RtnefSSSIJbeIxO2sbfxRFo=</ns3:HashValue>
                </ns1:attFile>
            </ns1:InvestigationalAvailability>
            <ns1:DisseminationPlan>
                <ns1:attFile>
                    <ns2:FileName>Dissemination_Plan_(Aim_3)_aw.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/5096049/HSCTA"
/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">Pb/Mn5CSpH1TMRKWLK8C+tS9NYc=</ns3:HashValue>
                </ns1:attFile>
            </ns1:DisseminationPlan>
        </ns1:ProtocolSynopsis>
        <ns1:OtherClinicalTrialAttachment>
            <ns2:AttachedFile>
                <ns2:FileName>Intervention_Manual_Materials_0_Contents_Table.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/441410/HSCTA"/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">wl8c4gPcAcQMWmQGIZGI+NS7YjA=</ns3:HashValue>
            </ns2:AttachedFile>
            <ns2:AttachedFile>
                <ns2:FileName>Intervention_Manual_Materials_1_Resources_Manu.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/441411/HSCTA"/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">C7PkGYUI3BiiK8brql5Ae5ffC88=</ns3:HashValue>
            </ns2:AttachedFile>
            <ns2:AttachedFile>
                <ns2:FileName>Intervention_Manual_Materials_2_IPSRT_Treatmen.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/441412/HSCTA"/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">S9HvXSKpyioffYKuRwceAEe/u00=</ns3:HashValue>
            </ns2:AttachedFile>
            <ns2:AttachedFile>
                <ns2:FileName>Intervention_Manual_Materials_3__Actigraphy_Co.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/44143112/HSCTA"/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">nXSm1mo6S+/uAfY+Jjrnmk5rS+k=</ns3:HashValue>
            </ns2:AttachedFile>
            <ns2:AttachedFile>
                <ns2:FileName>Intervention_Manual_Materials_4_Actigraphy_Deb.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/44143212/HSCTA"/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">DvtpngLR0aW/BxvUZBMC2LdygQ0=</ns3:HashValue>
            </ns2:AttachedFile>
            <ns2:AttachedFile>
                <ns2:FileName>Intervention_Manual_Materials_5_IPSRT_Therapy_.pdf</ns2:FileName>
                <ns2:MimeType>application/pdf</ns2:MimeType>
```

```xml
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/44143213/HSCTA"/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">csdzC4mYudoqeaGzV7fHuMiF7b4=</ns3:HashValue>
                </ns2:AttachedFile>
                <ns2:AttachedFile>
                    <ns2:FileName>Intervention_Manual_Materials_6_HL_Manual.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/44143412/HSCTA"/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">zm5zaEClPwufRzcCHktKObkFKFY=</ns3:HashValue>
                </ns2:AttachedFile>
                <ns2:AttachedFile>
                    <ns2:FileName>Intervention_Manual_Materials_7_HL_Services_Ch.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/44143125/HSCTA"/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">kQEAOpdaDrWpfG+HzNVKpWgnPWw=</ns3:HashValue>
                </ns2:AttachedFile>
                <ns2:AttachedFile>
                    <ns2:FileName>Intervention_Manual_Materials_8_Treatment_Targ.pdf</ns2:FileName>
                    <ns2:MimeType>application/pdf</ns2:MimeType>
                    <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/44143126/HSCTA"/>
                    <ns3:HashValue ns3:hashAlgorithm="SHA-1">swaYa/1BmQtfhPwU8W9NKnCfLQg=</ns3:HashValue>
                </ns2:AttachedFile>
            </ns1:OtherClinicalTrialAttachment>
        </ns1:HumanSubjectStudy_3_0>
    </ns4:HsctStudy>
```

PostSubmissionInfoType

#	Element Name	Description	XSD Complex Type Used
1	seriousAdverseEvents	Flag indicating if there are serious adverse events. Valid values: Yes/No/Not Applicable	
2	moreFrequentAdverseEvents	Flag indicating if there are more frequent adverse events. Valid values: Yes/No/Not Applicable	
3	studyStartDate	Anticipated/actual study start date. Value Anticipated/Actual followed by a date.	
4	studyPrimaryCompletionDate	Anticipated/actual primary completion date of the study. Value Anticipated/Actual followed by a date.	
5	studyFinalCompletionDate	Anticipated/actual final completion date of the study. Value Anticipated/Actual followed by a date.	
6	enrollmentAndRandomization	Enrollment and randomization type data. It is of type EnrollmentAndRandomizationType.	EnrollmentAndRandomizationType of HsctStudy.xsd
7	completionOfPrimaryEndpointAnalysis	Anticipated/actual primary endpoint analysis completion date. Value Anticipated/Actual followed by a date.	
8	completionOfSecondaryEndpointAnalysis	Anticipated/actual secondary endpoint analysis completion date. Value Anticipated/Actual followed by a date.	
9	reportingOfResults	Date when the results was/will be reported. Value Anticipated/Actual followed by a date.	
10	applicableClinicalTrialUnderFdaa	Flag specifying if the clinical trial is acceptable under FDSS. Valid values: Yes/No	

EnrollmentAndRandomizationType

#	Element Name	Description
1	percent25RecruitedBy	Anticipated/actual completion date for 25% of the recruitment. Value Anticipated/Actual followed by a date.
2	percent50RecruitedBy	Anticipated/actual completion date for 50% of the recruitment. Value Anticipated/Actual followed by a date.
3	percent75RecruitedBy	Anticipated/actual completion date for 75% of the recruitment. Value Anticipated/Actual followed by a date.

4	percent100RecruitedBy	Anticipated/actual completion date for 100% of the recruitment. Value Anticipated/Actual followed by a date.

Sample XML:

```
sd PostSubmissionInfo

<postSubmissionInfo>
        <seriousAdverseEvents>Y: Yes</seriousAdverseEvents>
        <moreFrequentAdverseEvents>N: No</moreFrequentAdverseEvents>
        <studyStartDate>
                <dateValue>2017-01-01-05:00</dateValue>
                <anticipatedActual>Anticipated</anticipatedActual>
        </studyStartDate>
        <studyPrimaryCompletionDate>
                <dateValue>2017-01-01-05:00</dateValue>
                <anticipatedActual>Actual</anticipatedActual>
        </studyPrimaryCompletionDate>
        <studyFinalCompletionDate>
                <dateValue>2017-01-01-05:00</dateValue>
                <anticipatedActual>Actual</anticipatedActual>
        </studyFinalCompletionDate>
        <enrollmentAndRandomization>
                <percent25RecruitedBy>
                        <dateValue>2017-01-01-05:00</dateValue>
                        <anticipatedActual>Actual</anticipatedActual>
                </percent25RecruitedBy>
                <percent50RecruitedBy>
                        <dateValue>2017-01-01-05:00</dateValue>
                        <anticipatedActual>Actual</anticipatedActual>
                </percent50RecruitedBy>
                <percent75RecruitedBy>
                        <dateValue>2017-01-01-05:00</dateValue>
                        <anticipatedActual>Actual</anticipatedActual>
                </percent75RecruitedBy>
                <percent100RecruitedBy>
                        <dateValue>2017-01-01-05:00</dateValue>
                        <anticipatedActual>Actual</anticipatedActual>
                </percent100RecruitedBy>
        </enrollmentAndRandomization>
        <completionOfPrimaryEndpointAnalysis>
                <dateValue>2017-01-01-05:00</dateValue>
                <anticipatedActual>Actual</anticipatedActual>
        </completionOfPrimaryEndpointAnalysis>
        <completionOfSecondaryEndpointAnalysis>
                <dateValue>2017-01-01-05:00</dateValue>
                <anticipatedActual>Actual</anticipatedActual>
        </completionOfSecondaryEndpointAnalysis>
        <reportingOfResults>
                <dateValue>2017-01-01-05:00</dateValue>
                <anticipatedActual>Actual</anticipatedActual>
        </reportingOfResults>
        <applicableClinicalTrialUnderFdaa>Y: Yes
        </applicableClinicalTrialUnderFdaa>
        <registrationAndReportingCertification>N: No
        </registrationAndReportingCertification>
</postSubmissionInfo>
```

IerParticipantDataType

#	Element Name	Description	XSD Complex Type Used
1	ierId	eRA Inclusion Enrollment Report ID	
2	participantData	List of participant data type values.	ParticipantDataType of HsctStudy-V3.0.xsd
3	participantDataAttachment	Paticipant level data need to be submitted in CSV format. This attribute will hold attachment details for this attachment **NOTE : Starting HsctStudy-V3.0 HsctExternalService will accept new Participant Level data only in attachment format**	AttachedFileDataType of Attachments-V1.0

ParticipantDataType

#	Element Name	Description
1	race	Race code. Valid values: AmericanIndian Asian Hawaiian Black White MultipleRace Unknown
2	ethnicity	Ethnicity code. Valid values: Hispanic Not Hispanic Unknown
3	gender	Valid values: Male Female Unknown
4	ageType	Age unit code. Valid values: Years Months Weeks Days Hours Minutes Ninety Plus Unknown
5	age	Age of the participant.

Sample XML for ierPartcipantData:

sd IER Participant Data

```xml
<ierParticipantData>
        <ierId>1008823</ierId>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>1</age>
                <ageType>Years</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>2</age>
                <ageType>Months</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>3</age>
                <ageType>Weeks</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>4</age>
                <ageType>Days</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>5</age>
                <ageType>Hours</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>6</age>
                <ageType>Minutes</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>7</age>
                <ageType>Unknown</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Male</gender>
                <age>91</age>
                <ageType>Ninety Plus</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
                <gender>Female</gender>
                <age>8</age>
                <ageType>Years</ageType>
        </participantData>
        <participantData>
                <race>AmericanIndian</race>
                <ethnicity>Hispanic</ethnicity>
```

```
            <ethnicity>Hispanic</ethnicity>
            <gender>Unknown</gender>
            <age>9</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>AmericanIndian</race>
            <ethnicity>Not Hispanic</ethnicity>
            <gender>Male</gender>
            <age>10</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>AmericanIndian</race>
            <ethnicity>Unknown</ethnicity>
            <gender>Male</gender>
            <age>11</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>Asian</race>
            <ethnicity>Hispanic</ethnicity>
            <gender>Male</gender>
            <age>12</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>Black</race>
            <ethnicity>Hispanic</ethnicity>
            <gender>Male</gender>
            <age>13</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>Hawaiian</race>
            <ethnicity>Hispanic</ethnicity>
            <gender>Male</gender>
            <age>14</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>White</race>
            <ethnicity>Hispanic</ethnicity>
            <gender>Male</gender>
            <age>15</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>MultipleRace</race>
            <ethnicity>Hispanic</ethnicity>
            <gender>Male</gender>
            <age>16</age>
            <ageType>Years</ageType>
    </participantData>
    <participantData>
            <race>Unknown</race>
            <ethnicity>Hispanic</ethnicity>
            <gender>Male</gender>
            <age>17</age>
            <ageType>Years</ageType>
    </participantData>
</ierParticipantData>
```

AttachedFileDataType

#	Element Name	Description
1	FileName	File name of the attachment
2	MimeType	Mime type of the file
3	FileLocation	DocService location of the file
4	HashValue	Hashvalue provided by DocService for this document

Sample Attachment section:

```
<ns4:ierParticipantData>
        <ns4:ierId>-1</ns4:ierId>
        <ns4:participantDataAttachment>
                <ns2:FileName>ParticipantLevelData-Template.csv</ns2:FileName>
                <ns2:MimeType>text/csv</ns2:MimeType>
                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/41507785
/HSCTA"/>
                <ns3:HashValue ns3:hashAlgorithm="SHA-1">BAQOue13GPEeIyT+n6A4fEBV5FY=</ns3:HashValue>
        </ns4:participantDataAttachment>
</ns4:ierParticipantData>
```

Sample CSV file :
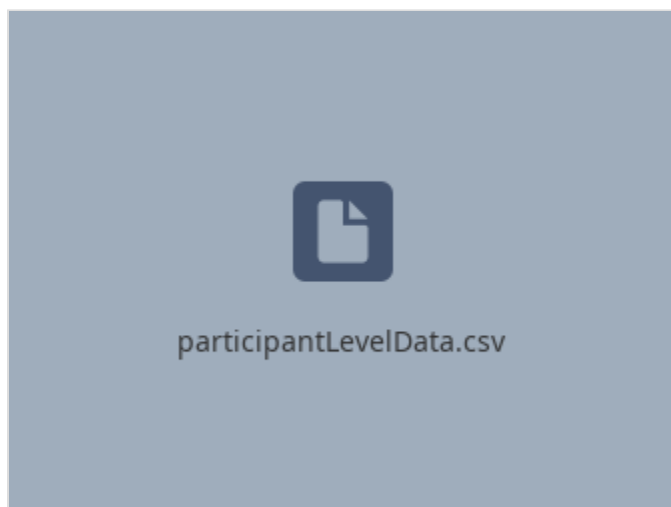
HsctDelayedOnsetStudy

#	Element Name	Description
1	studyId	Study ID
2	studyTitle	Study Title
3	anticipatedClinicalTrial	Anticipated Clinical Trial code. Valid values: Yes/No
4	Justification	Justification attachment path

Sample XML:

```
sd HsctDelayedOnsetStudy

<HsctDelayedOnsetStudy>
        <studyId>1008807</studyId>
        <studyTitle>Delayed Onset Study #4</studyTitle>
        <anticipatedClinicalTrial>Y: Yes</anticipatedClinicalTrial>
        <justification>
                <attFile>
                        <ns2:FileName>ASSIST_ClincialTrial_DelayOnsetStudy4.pdf</ns2:FileName>
                        <ns2:MimeType>application/pdf</ns2:MimeType>
                        <ns2:FileLocation att:href="/docservice/dataservices/document/keyId/3022/HSCTA" />
                </attFile>
        </justification>
</HsctDelayedOnsetStudy>
```

3. HSS ExternalService Submission Service

3.1 Approach

When study information has to be uploaded or updated for an application, the caller will provide the eRA Application ID or contractNumber or (serialNumber and adminPhsOrgCode) . If appId is provided we ignore contractNumber, serialNumber and adminPhsOrgCode fields, apart from that it will also take list of regular and delayed-onset studies . In the application header we have refreshClinicalTrials field, this field is to refresh data from clinicaltrials.gov based on the ClinicalTrialsIdentifier in HumanSubjectStudy.

When a study is added, the caller should provide no study ID or a negative number as the study ID and IER IDs. The service will generate new IDs for the study and IERs. If the caller is providing participant data for an IER, both the IER and participant data should have the same negative IER ID so that the service can associate them.

When adding or modifying study , HsctStudy.SourceUniqueValue or HumanSubjectStudy.studyId is required.

When a study is modified, the caller should provide the study ID and IER IDs for existing IERs.

The caller will upload all the necessary study attachments into eRA using eRA Document Service. The document service will provide a unique ID for each uploaded attachment. The caller will then send the HREF for those attachments as part of the study data. See section 5.2 for details
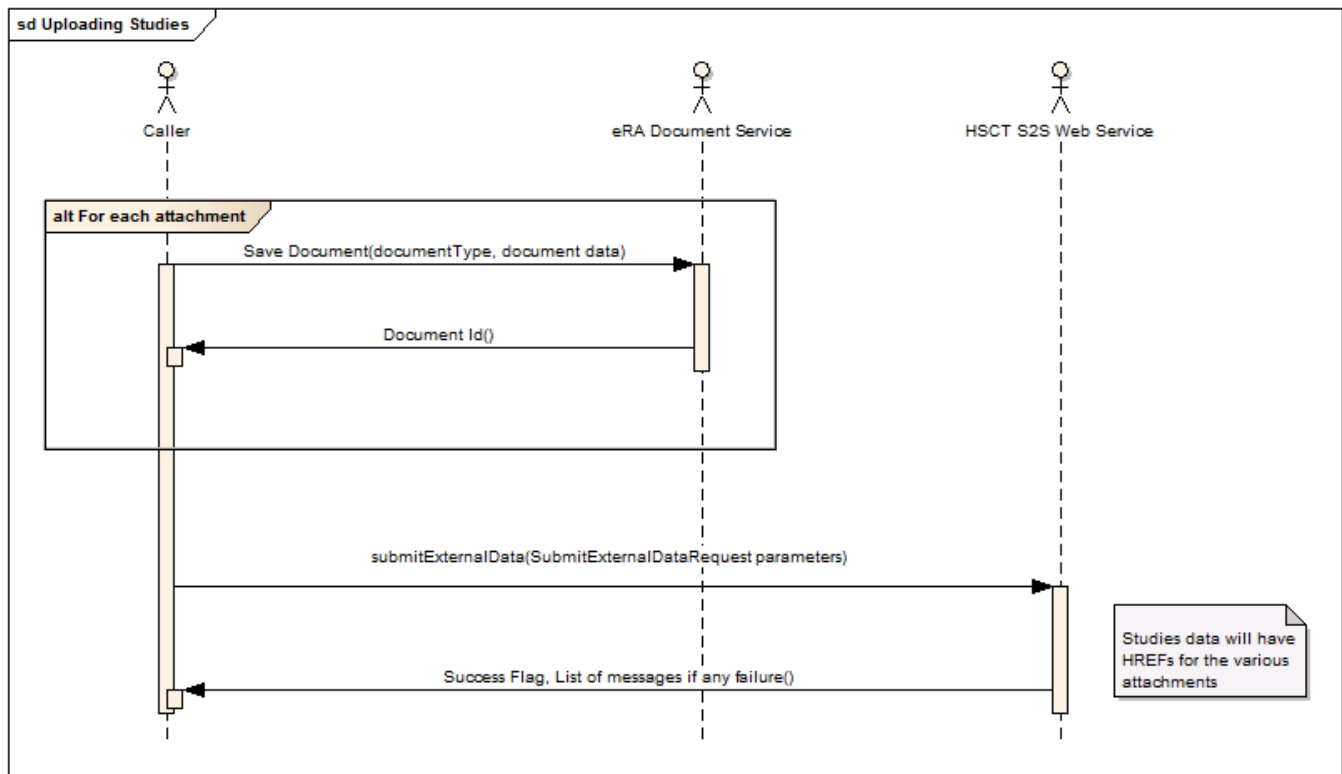
3.2 Submitting HSS Study Data - submitExternalData

The name of the method to submit study data is "submitExternalData". The API have capability to accept and process studies submitted for multiple applications in single request. **applicationsListWithStudies** needs to be repeated with appropriate application header info and studies data.

Web Attributes	Details
Endpoint	/submitExternalData
Method	POST
Path Params	**NA**
Request Media Type	application/xml
Request Payload	

Request

```
<hsc:SubmitExternalDataRequest
        xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService"
xmlns:ns1="http://era.nih.gov/hsct/HsctStudy-V3.0"
xmlns:ns4="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0"
xmlns:att="http://apply.grants.gov/system/Attachments-V1.0"
xmlns:glob="http://apply.grants.gov/system/Global-V1.0"
xmlns:hsc2="http://era.nih.gov/hsct/hsctDelayedOnsetStudy-V1.0">

  <hsc:applicationsListWithStudies>
          <hsc:applicationHeaderInfo>
        <hsc:eraApplicationId>10915401</hsc:eraApplicationId>
         <hsc:refreshClinicalTrials>Y</hsc:refreshClinicalTrials>
      </hsc:applicationHeaderInfo>
```

```xml
    <ns4:HsctStudy xmlns:ns1="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0" xmlns:
ns2="http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns3=
"http://apply.grants.gov/system/Global-V1.0" xmlns:ns4="http://era.nih.gov/hsct/HsctStudy-V3.0">
  <ns1:HumanSubjectStudy_3_0 ns1:FormVersion="3.0">
    <ns1:Study_id>-1</ns1:Study_id>
    <ns1:StudyTitle>New study 2 Via S2S_09172024</ns1:StudyTitle>
    <ns1:ExemptFedReg>Y: Yes</ns1:ExemptFedReg>
    <ns1:ExemptionNumbers>
      <ns1:ExemptionNumber>E1</ns1:ExemptionNumber>
      <ns1:ExemptionNumber>E2</ns1:ExemptionNumber>
    </ns1:ExemptionNumbers>
    <ns1:ClinicalTrialQuestionnaire>
      <ns1:HumanSubjectsIndicator>Y: Yes</ns1:HumanSubjectsIndicator>
      <ns1:InterventionAssigned>Y: Yes</ns1:InterventionAssigned>
      <ns1:EvaluateIntervention>Y: Yes</ns1:EvaluateIntervention>
      <ns1:HealthRelatedOutcome>Y: Yes</ns1:HealthRelatedOutcome>
    </ns1:ClinicalTrialQuestionnaire>
    <ns1:ClinicalTrialsIdentifier>NCT02879812</ns1:ClinicalTrialsIdentifier>
    <ns1:StudyPopulationCharacteristics>
      <ns1:StudyConditions>Fever</ns1:StudyConditions>
      <ns1:StudyConditions>Malaria</ns1:StudyConditions>
      <ns1:StudyConditions>Diagnosis</ns1:StudyConditions>
      <ns1:StudyConditions>Referral</ns1:StudyConditions>
      <ns1:EligibilityCriteria>Inclusion Criteria:

          - Patients with fever

          - uncomplicted malaria

        Exclusion Criteria:

          - Complicated malaria

          - known allergic reactions to Lumartem</ns1:EligibilityCriteria>
      <ns1:AgeLimits>
        <ns1:MinimumAge>
          <ns1:Age>1</ns1:Age>
          <ns1:AgeType>Months</ns1:AgeType>
        </ns1:MinimumAge>
        <ns1:MaximumAge>
          <ns1:Age>71</ns1:Age>
          <ns1:AgeType>Years</ns1:AgeType>
        </ns1:MaximumAge>
      </ns1:AgeLimits>
      <ns1:InclusionOfIndividualsAcrossLifespan>
                        <ns1:attFile>
                            <ns2:FileName>1-AdditionalSKP-ProjectY1.pdf</ns2:FileName>
                            <ns2:MimeType>application/pdf</ns2:MimeType>
                            <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/1990282/HSCTA"/>
                            <ns3:HashValue ns3:hashAlgorithm="SHA-1">qpoDFCEd5lx0a2EhohU7QxSmi2w=<
/ns3:HashValue>
                        </ns1:attFile>
                    </ns1:InclusionOfIndividualsAcrossLifespan>
        <ns1:InclusionOfWomenAndMinorities>
        <ns1:attFile>
          <ns2:FileName>ASSIST_CT_Study1Appendix3_OV.pdf</ns2:FileName>
          <ns2:MimeType>application/pdf</ns2:MimeType>
          <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990281
/HSCTA"/>
          <ns3:HashValue ns3:hashAlgorithm="SHA-1">+wldJvNoLIZxKueCkjb4u0+Jhf8=</ns3:HashValue>
        </ns1:attFile>
      </ns1:InclusionOfWomenAndMinorities>
      <ns1:RecruitmentAndRetentionPlan>
        <ns1:attFile>
          <ns2:FileName>CT_StdyTmln2_AD.pdf</ns2:FileName>
          <ns2:MimeType>application/pdf</ns2:MimeType>
          <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990280
/HSCTA"/>
          <ns3:HashValue ns3:hashAlgorithm="SHA-1">qpoDFCEd5lx0a2EhohU7QxSmi2w=</ns3:HashValue>
        </ns1:attFile>
```

```xml
          </ns1:RecruitmentAndRetentionPlan>
        <ns1:RecruitmentStatus>Completed</ns1:RecruitmentStatus>
        <ns1:StudyTimeline>
          <ns1:attFile>
            <ns2:FileName>ASSIST_CT_Inclusion_of_Individ_Across_Lifespan.pdf</ns2:FileName>
            <ns2:MimeType>application/pdf</ns2:MimeType>
            <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990279
/HSCTA"/>
            <ns3:HashValue ns3:hashAlgorithm="SHA-1">f03n6KRNpYqQJ1mvcMjPPjM8eVY=</ns3:HashValue>
          </ns1:attFile>
        </ns1:StudyTimeline>
        <ns1:FirstSubjectEnrollment>
          <ns1:EnrollmentDate>2010-09-01</ns1:EnrollmentDate>
          <ns1:AnticipatedActual>Actual</ns1:AnticipatedActual>
        </ns1:FirstSubjectEnrollment>
        <ns1:InclusionEnrollmentReport>
          <ns1:IER_id>-1</ns1:IER_id>
        <ns1:InclusionEnrollmentReportTitle>New title Some of 5</ns1:InclusionEnrollmentReportTitle>
          <ns1:ExistingDatasetOrResource>N: No</ns1:ExistingDatasetOrResource>
          <ns1:EnrollmentLocationType>Foreign</ns1:EnrollmentLocationType>
          <ns1:EnrollmentCountry>AUT: AUSTRIA</ns1:EnrollmentCountry>
          <ns1:EnrollmentLocations>Austria</ns1:EnrollmentLocations>
          <ns1:Planned>
            <ns1:NotHispanic>
              <ns1:Female>
                <ns1:AmericanIndian>1</ns1:AmericanIndian>
                <ns1:Asian>2</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:Total>3</ns1:Total>
              </ns1:Female>
              <ns1:Male>
                <ns1:AmericanIndian>0</ns1:AmericanIndian>
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>4564</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:Total>0</ns1:Total>
              </ns1:Male>
            </ns1:NotHispanic>
            <ns1:Hispanic>
              <ns1:Female>
                <ns1:AmericanIndian>2</ns1:AmericanIndian>
                <ns1:Asian>2637</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>66</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:Total>70</ns1:Total>
              </ns1:Female>
              <ns1:Male>
                <ns1:AmericanIndian>0</ns1:AmericanIndian>
                <ns1:Asian>0</ns1:Asian>
                <ns1:Hawaiian>0</ns1:Hawaiian>
                <ns1:Black>0</ns1:Black>
                <ns1:White>0</ns1:White>
                <ns1:MultipleRace>0</ns1:MultipleRace>
                <ns1:Total>0</ns1:Total>
              </ns1:Male>
            </ns1:Hispanic>
            <ns1:Total>
              <ns1:AmericanIndian>3</ns1:AmericanIndian>
              <ns1:Asian>4</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>0</ns1:Black>
              <ns1:White>66</ns1:White>
              <ns1:MultipleRace>0</ns1:MultipleRace>
              <ns1:Total>73</ns1:Total>
```

```xml
          </ns1:Total>
        </ns1:Planned>
        <ns1:Cumulative>
          <ns1:NotHispanic>
            <ns1:Female>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>11</ns1:Black>
              <ns1:White>67</ns1:White>
              <ns1:MultipleRace>100</ns1:MultipleRace>
              <ns1:UnknownRace>0</ns1:UnknownRace>
              <ns1:Total>178</ns1:Total>
            </ns1:Female>
            <ns1:Male>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>0</ns1:Black>
              <ns1:White>0</ns1:White>
              <ns1:MultipleRace>0</ns1:MultipleRace>
              <ns1:UnknownRace>0</ns1:UnknownRace>
              <ns1:Total>0</ns1:Total>
            </ns1:Male>
            <ns1:UnknownGender>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>0</ns1:Black>
              <ns1:White>0</ns1:White>
              <ns1:MultipleRace>0</ns1:MultipleRace>
              <ns1:UnknownRace>0</ns1:UnknownRace>
              <ns1:Total>0</ns1:Total>
            </ns1:UnknownGender>
          </ns1:NotHispanic>
          <ns1:Hispanic>
            <ns1:Female>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>0</ns1:Black>
              <ns1:White>0</ns1:White>
              <ns1:MultipleRace>0</ns1:MultipleRace>
              <ns1:UnknownRace>0</ns1:UnknownRace>
              <ns1:Total>0</ns1:Total>
            </ns1:Female>
            <ns1:Male>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>0</ns1:Black>
              <ns1:White>0</ns1:White>
              <ns1:MultipleRace>0</ns1:MultipleRace>
              <ns1:UnknownRace>0</ns1:UnknownRace>
              <ns1:Total>0</ns1:Total>
            </ns1:Male>
            <ns1:UnknownGender>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
              <ns1:Hawaiian>0</ns1:Hawaiian>
              <ns1:Black>0</ns1:Black>
              <ns1:White>0</ns1:White>
              <ns1:MultipleRace>0</ns1:MultipleRace>
              <ns1:UnknownRace>0</ns1:UnknownRace>
              <ns1:Total>0</ns1:Total>
            </ns1:UnknownGender>
          </ns1:Hispanic>
          <ns1:UnknownEthnicity>
            <ns1:Female>
              <ns1:AmericanIndian>0</ns1:AmericanIndian>
              <ns1:Asian>0</ns1:Asian>
```

```xml
            <ns1:Hawaiian>0</ns1:Hawaiian>
            <ns1:Black>0</ns1:Black>
            <ns1:White>0</ns1:White>
            <ns1:MultipleRace>0</ns1:MultipleRace>
            <ns1:UnknownRace>0</ns1:UnknownRace>
            <ns1:Total>0</ns1:Total>
          </ns1:Female>
          <ns1:Male>
            <ns1:AmericanIndian>0</ns1:AmericanIndian>
            <ns1:Asian>0</ns1:Asian>
            <ns1:Hawaiian>0</ns1:Hawaiian>
            <ns1:Black>0</ns1:Black>
            <ns1:White>0</ns1:White>
            <ns1:MultipleRace>0</ns1:MultipleRace>
            <ns1:UnknownRace>0</ns1:UnknownRace>
            <ns1:Total>0</ns1:Total>
          </ns1:Male>
          <ns1:UnknownGender>
            <ns1:AmericanIndian>0</ns1:AmericanIndian>
            <ns1:Asian>0</ns1:Asian>
            <ns1:Hawaiian>0</ns1:Hawaiian>
            <ns1:Black>0</ns1:Black>
            <ns1:White>0</ns1:White>
            <ns1:MultipleRace>0</ns1:MultipleRace>
            <ns1:UnknownRace>0</ns1:UnknownRace>
            <ns1:Total>0</ns1:Total>
          </ns1:UnknownGender>
        </ns1:UnknownEthnicity>
        <ns1:Total>
          <ns1:AmericanIndian>10</ns1:AmericanIndian>
          <ns1:Asian>20</ns1:Asian>
          <ns1:Hawaiian>0</ns1:Hawaiian>
          <ns1:Black>30</ns1:Black>
          <ns1:White>77</ns1:White>
          <ns1:MultipleRace>89</ns1:MultipleRace>
          <ns1:UnknownRace>0</ns1:UnknownRace>
          <ns1:Total>0</ns1:Total>
        </ns1:Total>
      </ns1:Cumulative>
    </ns1:InclusionEnrollmentReport>
  </ns1:StudyPopulationCharacteristics>
  <ns1:ProtectionMonitoringPlans>
    <ns1:ProtectionOfHumanSubjects>
      <ns1:attFile>
        <ns2:FileName>ASSIST_CT_PrtctofHmnSbjct4.pdf</ns2:FileName>
        <ns2:MimeType>application/pdf</ns2:MimeType>
        <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990278
/HSCTA"/>
        <ns3:HashValue ns3:hashAlgorithm="SHA-1">iGEAZlVUtPXFe1b6L9mfMj0zKXw=</ns3:HashValue>
      </ns1:attFile>
    </ns1:ProtectionOfHumanSubjects>
    <ns1:MultiSiteStudy>N: No</ns1:MultiSiteStudy>
    <ns1:DataSafetyMonitoringPlan>
      <ns1:attFile>
        <ns2:FileName>ASSIST_CT_InclnWmnMnty_AD_2.pdf</ns2:FileName>
        <ns2:MimeType>application/pdf</ns2:MimeType>
        <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990277
/HSCTA"/>
        <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWMyG+xOj3Reiq0=</ns3:HashValue>
      </ns1:attFile>
    </ns1:DataSafetyMonitoringPlan>
    <ns1:BoardAppointed>N: No</ns1:BoardAppointed>
    <ns1:StudyTeamStructure>
      <ns1:attFile>
        <ns2:FileName>ASSIST_CT_InclWmnMty_AMC1.pdf</ns2:FileName>
        <ns2:MimeType>application/pdf</ns2:MimeType>
        <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990276
/HSCTA"/>
        <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWMyG+xOj3Reiq0=</ns3:HashValue>
      </ns1:attFile>
    </ns1:StudyTeamStructure>
```

```xml
        </ns1:ProtectionMonitoringPlans>
      <ns1:ProtocolSynopsis>
        <ns1:StudyDesign>
          <ns1:DetailedDescription>test design</ns1:DetailedDescription>
          <ns1:PrimaryPurpose>Diagnostics</ns1:PrimaryPurpose>
          <ns1:Interventions>
            <ns1:InterventionType>Device (including sham)</ns1:InterventionType>
            <ns1:InterventionName>Rapid diagnostic test</ns1:InterventionName>
            <ns1:InterventionDescription>Diagnosis of malaria using rapid diagnostic test</ns1:
InterventionDescription>
          </ns1:Interventions>
          <ns1:Interventions>
            <ns1:InterventionType>Drug (including placebo)</ns1:InterventionType>
            <ns1:InterventionName>Lumartem</ns1:InterventionName>
            <ns1:InterventionDescription>Presumptive treatment of malaria/fever</ns1:
InterventionDescription>
          </ns1:Interventions>
          <ns1:StudyPhase>Phase 2</ns1:StudyPhase>
          <ns1:NIHPhase3ClinicalTrial>Y: Yes</ns1:NIHPhase3ClinicalTrial>
          <ns1:InterventionModel>Parallel</ns1:InterventionModel>
          <ns1:Masking>N: No</ns1:Masking>
          <ns1:MaskingType>
            <ns1:Participant>N: No</ns1:Participant>
            <ns1:CareProvider>N: No</ns1:CareProvider>
            <ns1:Investigator>N: No</ns1:Investigator>
            <ns1:OutcomesAssessor>N: No</ns1:OutcomesAssessor>
          </ns1:MaskingType>
          <ns1:Allocation>Randomized</ns1:Allocation>
        </ns1:StudyDesign>
        <ns1:OutcomesMeasures>
          <ns1:OutcomeName>Appropriateness of treatment</ns1:OutcomeName>
          <ns1:OutcomeType>Primary</ns1:OutcomeType>
          <ns1:TimeFrame>36 months</ns1:TimeFrame>
          <ns1:OutcomeDescription>test</ns1:OutcomeDescription>
        </ns1:OutcomesMeasures>
        <ns1:OutcomesMeasures>
          <ns1:OutcomeName>Appropriateness of referral of complicated malaria cases</ns1:OutcomeName>
          <ns1:OutcomeType>Secondary</ns1:OutcomeType>
          <ns1:TimeFrame>36 months</ns1:TimeFrame>
          <ns1:OutcomeDescription>test1</ns1:OutcomeDescription>
        </ns1:OutcomesMeasures>
        <ns1:StatisticalDesignPower>
          <ns1:attFile>
            <ns2:FileName>ASSIST_CT_DOnsetStudy3.pdf</ns2:FileName>
            <ns2:MimeType>application/pdf</ns2:MimeType>
            <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990275
/HSCTA"/>
            <ns3:HashValue ns3:hashAlgorithm="SHA-1">6P/GJW08dHsKQsPAkLREhW1sncA=</ns3:HashValue>
          </ns1:attFile>
        </ns1:StatisticalDesignPower>
        <ns1:SubjectParticipationDuration>1 month</ns1:SubjectParticipationDuration>
        <ns1:FDARegulatedIntervention>N: No</ns1:FDARegulatedIntervention>
        <ns1:ApplicableClinicalTrial>Y: Yes</ns1:ApplicableClinicalTrial>
        <ns1:DisseminationPlan>
          <ns1:attFile>
            <ns2:FileName>ASSIST_CT_DisseminPlan_AMC1.pdf</ns2:FileName>
            <ns2:MimeType>application/pdf</ns2:MimeType>
            <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/1990274
/HSCTA"/>
            <ns3:HashValue ns3:hashAlgorithm="SHA-1">Sw1aJewy3joxSijfLZ+7PHaS2HE=</ns3:HashValue>
          </ns1:attFile>
        </ns1:DisseminationPlan>
      </ns1:ProtocolSynopsis>
    </ns1:HumanSubjectStudy_3_0>
        <ns4:postSubmissionInfo>
        <ns4:seriousAdverseEvents>Y: Yes</ns4:seriousAdverseEvents>
        <ns4:moreFrequentAdverseEvents>N: No</ns4:moreFrequentAdverseEvents>
        <ns4:studyStartDate>
            <ns4:dateValue>2022-04-12-05:00</ns4:dateValue>
            <ns4:anticipatedActual>Actual</ns4:anticipatedActual>
        </ns4:studyStartDate>
```

```
                <ns4:studyPrimaryCompletionDate>
                    <ns4:dateValue>2027-05-11-04:00</ns4:dateValue>
                    <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                </ns4:studyPrimaryCompletionDate>
                <ns4:studyFinalCompletionDate>
                    <ns4:dateValue>2027-08-11-04:00</ns4:dateValue>
                    <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                </ns4:studyFinalCompletionDate>
                <ns4:enrollmentAndRandomization>
                    <ns4:percent25RecruitedBy>
                        <ns4:dateValue>2027-01-13-05:00</ns4:dateValue>
                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                    </ns4:percent25RecruitedBy>
                    <ns4:percent50RecruitedBy>
                        <ns4:dateValue>2027-02-01-05:00</ns4:dateValue>
                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                    </ns4:percent50RecruitedBy>
                    <ns4:percent75RecruitedBy>
                        <ns4:dateValue>2027-03-01-05:00</ns4:dateValue>
                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                    </ns4:percent75RecruitedBy>
                    <ns4:percent100RecruitedBy>
                        <ns4:dateValue>2027-10-21-04:00</ns4:dateValue>
                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                    </ns4:percent100RecruitedBy>
                </ns4:enrollmentAndRandomization>
                <ns4:completionOfPrimaryEndpointAnalysis>
                    <ns4:dateValue>2027-06-01-04:00</ns4:dateValue>
                    <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                </ns4:completionOfPrimaryEndpointAnalysis>
                <ns4:completionOfSecondaryEndpointAnalysis>
                    <ns4:dateValue>2027-07-01-04:00</ns4:dateValue>
                    <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                </ns4:completionOfSecondaryEndpointAnalysis>
                <ns4:reportingOfResults>
                    <ns4:dateValue>2027-08-01-04:00</ns4:dateValue>
                    <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                </ns4:reportingOfResults>
                <ns4:applicableClinicalTrialUnderFdaa>Y: Yes</ns4:applicableClinicalTrialUnderFdaa>
                <ns4:registrationAndReportingCertification>N: No</ns4:
registrationAndReportingCertification>
        </ns4:postSubmissionInfo>
    </ns4:HsctStudy>
</hsc:applicationsListWithStudies>
</hsc:SubmitExternalDataRequest>
```

Success Response	Http Status: **200 Ok**
	Example :

Response

```
<SubmitExternalDataResponse xmlns="http://era.nih.gov/hsct/HsctExternalService" xmlns:ns2="
http://era.nih.gov/hsct/HsctCommonTypes-V1.0">
    <success>true</success>
    <applicationsSubmitDataStatusList>
        <applicationHeaderInfo>
            <eraApplicationId>10915401</eraApplicationId>
            <refreshClinicalTrials>Y</refreshClinicalTrials>
        </applicationHeaderInfo>
        <isSuccess>true</isSuccess>
    </applicationsSubmitDataStatusList>
</SubmitExternalDataResponse>
```

Error Response	Http Status: **500**

```
{
    "code": "500",
    "message": " Error ID: 1729876216079 Could not unmarshal to [class gov.nih.era.hsct.
hsctexternalservice.auto.SubmitExternalDataRequest]: null; nested exception is javax.xml.bind.
UnmarshalException\n - with linked exception:\n[org.xml.sax.SAXParseException; lineNumber: 13;
columnNumber: 53; cvc-datatype-valid.1.2.1: '' is not a valid value for 'integer'.]"
}
```

3.3 Input Values

Information about application where studies will be associated;

SubmitExternalDataRequest

#	Element Name	Description	Rule	Error when rule is not met	Error Code	XSD Complex Type Used
1	applicationsListWith Studies	List of applications with Study Information	Minimum one application required	XSD error		ApplicationWithStudies of HsctExterna lService.xsd

ApplicationWithStudies

#	Element Name	Description	Rule	Error when rule is not met	Error Code	XSD Complex Type Used
1	application HeaderInfo	Header information about the application	Requir ed	XSD Error		ApplicationHeaderInfo of HsctExternalService.xsd
2	hsctStudy	List of regular studies. Either one of HsctStudy or HsctDelayedOnsetStudy is required.	Option al			HsctStudy of HsctStudy.xsd. Refer to section 7 for XSD and sample submit data request.
3	hsctDelaye dOnsetStudy	List of delayed-onset studies.Either one of HsctStudy or HsctDelayedOnsetStudy is required.	Option al			HsctDelayedOnsetStudy of HsctDelayedOnsetStudy. xsd. Refer to section 7 for XSD and sample submit data request.

ApplicationHeaderInfo

- Grants : eraApplicationId or (serialNumber and adminPhsOrgCode) is required. If studies need to be added under subproject then subproject eraApplicationId or (serialNumber , adminPhsOrgCode and subprojectId) is required.
- intramural : eraApplicationId or serialNumber and adminPhsOrgCode is required..
- Contracts: eraApplicationId or contractnumber is required.
- When refreshClinicalTrials flag is set to 'Y'; data will be refreshed from clinicaltrials.gov based on the ClinicalTrialsIdentifier in HumanSubjectStudy; refer to below table on what fields are populated from clinicaltrials.gov.

#	Element Name	Description	Rule	Error when rule is not met	Error Code	XSD Complex Type Used
1	eraApplicati onId	eRA application ID for which the studies need to be added/updated	Option al	XSD error	N/A	
2	contractNu mber	contract number for which the studies need to be added/updated. This is the column in appls_t. contract_num	Option al			
3	serialNumb er	serial number of the application for which the studies need to be added/updated. If applicationId is not provided we use serial number and adminPhsOrgCode to determine applicationId for Grants and Intramurals.	Option al			
4	adminPhsO rgCode	PHS organization that may administer, fund, and/or review an application; If applicationId is not provided we use serial number and adminPhsOrgCode to determine applicationId .	Option al			

| 5 | subprojectId | This identifies the subproject id for the complex application; If applicationId is not provided we use serial number adminPhsOrgCode and subprojectId to determine applicationId for Grants and Intramurals. | Option al | | | |
| 6 | refreshClini calTrials | A flag which represents if the eRA system should populate protocol elements from clinicaltrials. gov. | Requir ed | | | |

refreshClinicalTrials cell content:

Values:

Yes- To populate the latest protocol elements from clinicaltrials.gov

No - Not to populate the protocol elements received through the service

If the clinicaltrials.gov flag is set to "Yes" and the NCT# is provided for a study, the latest protocol elements from ClinicalTrials.gov will be used for the study instead of the values passed to the service.

The following Protocol Elements will be populated from CT.gov

• Study Title
• Conditions of Focus of Study
• Eligibility Criteria
• Age Limits
• Recruitment Status
• Brief Summary
• Narrative Study Description
• Primary Purpose
• Interventions
• Study Phase
• Intervention Model
• Masking
• Allocation
• Outcome Measures
• Study Start Date
• Study Primary Completion Date
• Study Final Completion Date

Sample XML for adding a new regular study and a delayed study is given below. Study ID and IER IDs should be null or negative. If participant data is given for an IER, both the IER and the participant data should have the same negative number. The following example adds one regular study and one delayed onset study. The regular study has 3 IERs. The first and third IERs have participation data. The participant data is associated to the IERs by having the same IER IDs -1 and -3.

```
<hsc:SubmitExternalDataRequest xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService"
xmlns:ns1="http://era.nih.gov/hsct/HsctStudy-V3.0"
xmlns:ns4="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0"
xmlns:att="http://apply.grants.gov/system/Attachments-V1.0"
xmlns:glob="http://apply.grants.gov/system/Global-V1.0"
xmlns:hsc2="http://era.nih.gov/hsct/hsctDelayedOnsetStudy-V1.0">
        <hsc:applicationsListWithStudies>
            <hsc:applicationHeaderInfo>
               <hsc:eraApplicationId>9947901</hsc:eraApplicationId>
               <hsc:refreshClinicalTrials>Y</hsc:refreshClinicalTrials>
            </hsc:applicationHeaderInfo>
                    <!-- Zero or more repetitions -->
        <ns4:HsctStudy xmlns:ns1="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0" xmlns:ns2="
http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns3="http://apply.grants.gov/system/Global-V1.0" xmlns:
ns4="http://era.nih.gov/hsct/HsctStudy-V3.0">
            <ns1:HumanSubjectStudy_3_0 ns1:FormVersion="3.0">
                <ns1:Study_id>-1</ns1:Study_id>
                <ns1:StudyTitle>New study via S2S 5112020</ns1:StudyTitle>
                <ns1:ExemptFedReg>Y: Yes</ns1:ExemptFedReg>
                <ns1:ExemptionNumbers>
                    <ns1:ExemptionNumber>E1</ns1:ExemptionNumber>
                    <ns1:ExemptionNumber>E5</ns1:ExemptionNumber>
                </ns1:ExemptionNumbers>
                <ns1:ClinicalTrialQuestionnaire>
                    <ns1:HumanSubjectsIndicator>Y: Yes</ns1:HumanSubjectsIndicator>
                    <ns1:InterventionAssigned>Y: Yes</ns1:InterventionAssigned>
                    <ns1:EvaluateIntervention>Y: Yes</ns1:EvaluateIntervention>
                    <ns1:HealthRelatedOutcome>Y: Yes</ns1:HealthRelatedOutcome>
                </ns1:ClinicalTrialQuestionnaire>
                <ns1:ClinicalTrialsIdentifier>NCT01194557</ns1:ClinicalTrialsIdentifier>
                <ns1:StudyPopulationCharacteristics>
                    <ns1:StudyConditions>Fever</ns1:StudyConditions>
                    <ns1:StudyConditions>Malaria</ns1:StudyConditions>
                    <ns1:StudyConditions>Diagnosis</ns1:StudyConditions>
```

```xml
                    <ns1:StudyConditions>Referral</ns1:StudyConditions>
                    <ns1:EligibilityCriteria>Inclusion Criteria:

        -   Patients with fever

        -   uncomplicted malaria

    Exclusion Criteria:

        -   Complicated malaria

        -   known allergic reactions to Lumartem</ns1:EligibilityCriteria>
                    <ns1:FirstSubjectEnrollment>
                        <ns1:EnrollmentDate>2010-09-01</ns1:EnrollmentDate>
                        <ns1:AnticipatedActual>Actual</ns1:AnticipatedActual>
                    </ns1:FirstSubjectEnrollment>
                    <ns1:InclusionEnrollmentReport>
                        <ns1:IER_id>-1</ns1:IER_id>
                        <ns1:Planned>
                        </ns1:Planned>
                        <ns1:Cumulative>
                        </ns1:Cumulative>
                    </ns1:InclusionEnrollmentReport>
                                    <ns1:InclusionEnrollmentReport>
                        <ns1:IER_id>-2</ns1:IER_id>
                        <ns1:Planned>
                        </ns1:Planned>
                        <ns1:Cumulative>
                        </ns1:Cumulative>
                    </ns1:InclusionEnrollmentReport>
                </ns1:StudyPopulationCharacteristics>
            </ns1:HumanSubjectStudy_3_0>
            <ns4:ierParticipantData>
                    <ns4:ierId>-1</ns4:ierId>
                                    <ns4:participantDataAttachment>
                                            <ns2:FileName>ParticipantLevelData-Template.csv</ns2:FileName>
                                            <ns2:MimeType>text/csv</ns2:MimeType>
                                            <ns2:FileLocation ns2:href="era://document/docservice
/dataservices/document/keyId/41507785/HSCTA"/>
                                            <ns3:HashValue ns3:hashAlgorithm="SHA-1"
>BAQOue13GPEeIyT+n6A4fEBV5FY=</ns3:HashValue>
                                    </ns4:participantDataAttachment>
            </ns4:ierParticipantData>
                    <ns4:ierParticipantData>
                <ns4:ierId>-2</ns4:ierId>
                                    <ns4:participantDataAttachment>
                                            <ns2:FileName>ParticipantLevelData-Template.csv</ns2:FileName>
                                            <ns2:MimeType>text/csv</ns2:MimeType>
                                            <ns2:FileLocation ns2:href="era://document/docservice
/dataservices/document/keyId/41507786/HSCTA"/>
                                            <ns3:HashValue ns3:hashAlgorithm="SHA-1"
>BAQOue13GPEeIyT+n6DsA4fASV5FY=</ns3:HashValue>
                                    </ns4:participantDataAttachment>
                </ns4:ierParticipantData>
            </ns4:HsctStudy>

                    <!-- Zero or more repetitions -->
            <hsc2:HsctDelayedOnsetStudy>
                        <hsc2:studyId>-2</hsc2:studyId>
                <hsc2:studyTitle>Delayed Study Title</hsc2:studyTitle>
                <hsc2:anticipatedClinicalTrial>Y: Yes</hsc2:anticipatedClinicalTrial>
                <hsc2:justification>
                    <hsc2:attFile>
                        <ns2:FileName>att:FileName</ns2:FileName>
                        <ns2:MimeType>att:MimeType</ns2:MimeType>
                        <ns2:FileLocation att:href="era://document/docservice/dataservices/document/keyId/532135
/HSCTA" />
                        <ns3:HashValue ns3:hashAlgorithm="">MA==</ns3:HashValue>
                    </hsc2:attFile>
                </hsc2:justification>
            </hsc2:HsctDelayedOnsetStudy>
```

```
        </hsc:applicationsListWithStudies>
      </hsc:SubmitExternalDataRequest>
```

3.4 Output Values

This is the response object that is returned for data submitted to HSCT ExternalService service.

- success : Indicates overall request status. If all applications are submitted without any errors, this status will be true. If any application from the request runs into exception or validation errors this attribute will be set to false indicating there is issue with one or more applications.
- responseMessage : Message indicating why the message is a success or failure
- applicationsSubmitDataStatusList : List of all the applications submitted along with it's status indicating there it was successful/error out along with error list.

Output Structure

SubmitExternalDataResponse

#	Element Name	Description	XSD Complex Type Used
1	success	Overall submission status	ApplicationHeaderInfo of HsctExternalService.xsd
2	responseMessage	Message indicating why the message is a success or failure	ResponseMessage of HsctCommonTypes.xsd
3	applicationsSubmitDataStatus List	status to specify if it is successful, there are errors/warnings by application	ApplicationStudiesSubmitDataStatus of HsctExternalService .xsd

ApplicationStudiesSubmitDataStatus

#	Element Name	Description	XSD Complex Type Used
1	applicationHeaderInfo	Header info of the application indicating this response belongs to which application	ApplicationHeaderInfo of HsctExternalService.xsd
2	isSuccess	Boolean specifying if the submission was successful or not	
3	messageList	List of messages in case of error or warning.	ResponseMessage of HsctCommonTypes.xsd

Sample XML:

Below sample shows how response will look like if there is 1 successful and 1 failed application.

```
<tns:SubmitExternalDataResponse>
  <tns:success>false</tns:success>
  <tns:responseMessage>
    <tns1:messageCode>Message Code</tns1:messageCode>
    <tns1:messageSeverity>Error</tns1:messageSeverity>
    <tns1:messageText>Error Text</tns1:messageText>
  </tns:responseMessage>
  <tns:applicationsSubmitDataStatusList>
    <tns:applicationHeaderInfo>
        <tns:eraApplicationId>9947901</tns:eraApplicationId>
    </tns:applicationHeaderInfo>
    <tns:isSuccess>true</tns:isSuccess>
  </tns:applicationsSubmitDataStatusList>
  <tns:applicationsSubmitDataStatusList>
    <tns:applicationHeaderInfo>
        <tns:eraApplicationId>9947902</tns:eraApplicationId>
    </tns:applicationHeaderInfo>
    <tns:isSuccess>false</tns:isSuccess>
    <tns:messageList>
      <tns1:messageCode>S2S_SVC_MSG_CODE_01</tns1:messageCode>
      <tns1:messageSeverity>Error</tns1:messageSeverity>
      <tns1:messageText>Project not available in eRA system.</tns1:messageText>
    </tns:messageList>
  </tns:applicationsSubmitDataStatusList>
</tns:SubmitExternalDataResponse>
```

ResponseMessage

#	Element Name	Description
1	messageCode	Code of the message. It will be used to cross reference with the web service.
2	messageSeverity	Message severity. Valid values: Error, Warning
3	messageText	Message text

5. Study Attachments

5.1 Retrieving Attachments

Each study may contain attachments. This web service will return only the HREFs for each of them. The calling system should make calls to eRA Document Service to get the data for the attachments using the HREF values.

Example of a HREF (3022 is the document key ID and HSCTA is the doc type in this example):
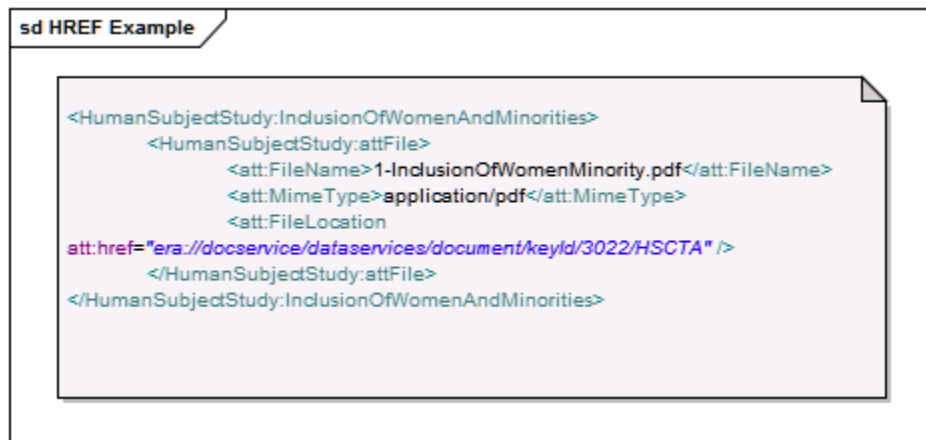
Refer to section 6.2 of the following document for retrieving the attachments:

https://inside.era.nih.gov/files/Document%20Service%20Technical%20User%20Guide_Cert-based%20Authentication.pdf

5.2 Uploading Attachments

Each study may contain attachments. The caller should upload them using eRA Document Service.The document service will return an ID for each uploaded document. The caller should provide the HREFs for the attachments as part of the study data as given by the following example.

Example of a HREF is in the above section 5.1

Refer to the following document for uploading the attachments using eRA Document Service.

https://inside.era.nih.gov/files/Document_Upload_User_Guide_DocService_HSCTA.pdf

6. HSS ExternalService SubmitPdfAttachment Service

6.1 Approach

When PHS Human Subjects study PDF form need to be uploaded for an application caller will provide Application ID along with pdf attachment and call this end point. Once the form is uploaded , HSCT system will perform business rule validation and return error/warning message to the caller if they have any failures . If there are no errors then HSCT system will return success response and process all the studies in the attachment asynchronously; it will also upload necessary documents that are part of each study attachment into eRA DocService Module.

This end point will allow submitting studies with Parent contract. If no child project is available for submitted Parent Contract then it will call CIMS Service to create shell project and attach study to this newly created child project.

Refer to section 1.3 for the roles that are required for the certificate account in order to call this end point.

Below is the high level data flow diagram
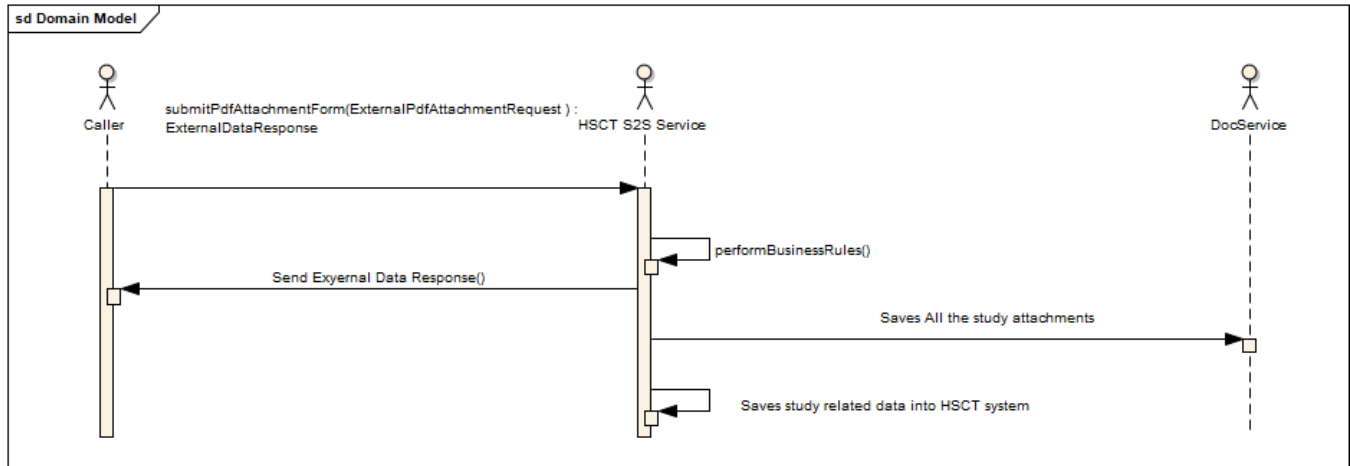
6.2 Submitting PHS Human Subjects study PDF form - submitPdfAttachmentForm

The name of the method to save PHS Human Subjects study PDF form is "submitPdfAttachmentForm".

Web Attributes	Details
Endpoint	/submitPdfAttachmentRequest
Method	POST
Path Params	Name: externalPdfAttachmentRequest Value: ``` { "applId" : 11125725 } ```
Request Media Type	multipart/form-data
Request Payload	``` ContentId: attachment ```

Success Response	Http Status: **200 Ok**
	Example :

Response

```
<SubmitExternalDataResponse xmlns="http://era.nih.gov/hsct/HsctExternalService" xmlns:ns2="http://era.nih.gov/hsct/HsctCommonTypes-V1.0">
    <success>true</success>
    <applicationsSubmitDataStatusList>
        <applicationHeaderInfo>
            <eraApplicationId>11125725</eraApplicationId>
            <refreshClinicalTrials>N</refreshClinicalTrials>
        </applicationHeaderInfo>
        <isSuccess>true</isSuccess>
    </applicationsSubmitDataStatusList>
</SubmitExternalDataResponse>
```

Error Response	
	• Http Status: **500**
	``` { "code": "500", "message": "Error in submitPdfAttachmentForm" } ```

6.3 Input Values

After successful authentication into HSS ExternalService web service, the following field information applies:

#	Element Name	Description	Rule	Error when rule is not met	Error Code
1	applId	eRA application ID for which the studies need to be uploaded	Required	XSD error	N/A
2	attachment	PHS Human Subjects study PDF form	Required	XSD error	N/A

6.4 Output Values

The Web Service will return the following results:

Output Structure

SubmitExternalDataResponse

#	Element Name	Description	XSD Complex Type Used
1	success	Overall submission status	ApplicationHeaderInfo of HsctExternalService.xsd
2	responseMessage	Message indicating why the message is a success or failure	ResponseMessage of HsctCommonTypes.xsd
3	applicationsSubmitDataStatus List	status to specify if it is successful, there are errors/warnings by application	ApplicationStudiesSubmitDataStatus of HsctExternalService.xsd

ApplicationStudiesSubmitDataStatus

- applicationHeaderInfo specifying this reponse belongs to which application id
- isSuccess specifying if the submission was successful or not
- List of messageList which contain the error messages

This is the response object that is returned for data submitted to HSCT ExternalService service. if 'isSuccess' value is 'True' then PHS Human Subjects study PDF form is processed asynchronously with in HSCT system.
If isSuccess is 'False' then appropriate error messages are returned in messageList. At this point studies that are sent in study PDF form will not be processed. All errors need to be resolved and request need to be resubmitted in order to process the studies. 'isSuccess' value is set to 'True' even though there are warning messages only; In this scenario study PDF form is processed with in HSCT system asynchronously.

#	Element Name	Description	XSD Complex Type Used
1	applicationHeaderInfo	Header info of the application indicating this response belongs to which application	ApplicationHeaderInfo of HsctExternalService.xsd
2	isSuccess	Boolean specifying if the submission was successful or not	
3	messageList	List of messages in case of error or warning.	ResponseMessage of HsctCommonTypes.xsd

ResponseMessage

#	Element Name	Description
1	messageCode	Code of the message. It will be used to cross reference with the web service.
2	messageSeverity	Message severity. Valid values: Error, Warning
3	messageText	Message text

Sample Response XML:

```
<tns:SubmitExternalDataResponse>
  <tns:success>false</tns:success>
  <tns:applicationsSubmitDataStatusList>
    <tns:applicationHeaderInfo>
        <tns:eraApplicationId>9947902</tns:eraApplicationId>
    </tns:applicationHeaderInfo>
    <tns:isSuccess>false</tns:isSuccess>
    <tns:messageList>
      <tns1:messageCode>000.25</tns1:messageCode>
      <tns1:messageSeverity>Error</tns1:messageSeverity>
      <tns1:messageText>The 5 pages.pdf attachment has been uploaded multiple times on the
PHS_HSCT_PostSubmission. Please make sure all files uploaded on the PHS_HSCT_PostSubmission have unique file
names.</tns1:messageText>
    </tns:messageList>
        <tns:messageList>
      <tns1:messageCode>000.25</tns1:messageCode>
      <tns1:messageSeverity>Error</tns1:messageSeverity>
      <tns1:messageText>The ASSIST_CT_Study1Appendix5.pdf has been uploaded multiple times on the
PHS_HSCT_PostSubmission. Please make sure all files uploaded on the PHS_HSCT_PostSubmission have unique file
names.</tns1:messageText>
    </tns:messageList>
  </tns:applicationsSubmitDataStatusList>
</tns:SubmitExternalDataResponse>
```

7. HSS Check Service

7.1 Approach

Fetches whether the application for HSS Check is passed validation and also fetches the messageList Details.

Refer to section 1.3 for the roles that are required for the certificate account in order to call this end point.

7.2 Perform HSS Check for Application - performHSSCheck

The name of the API to perform HSS Check is "performHSSCheck".

Web Attributes	Details
Endpoint	/performHSSCheck
Method	POST
Path Params	**NA**
Request Media Type	application/xml
Request Payload	**Request** ```<hsc:HSSCheckRequest xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService">
<hsc:applId>11046112</hsc:applId>
</hsc:HSSCheckRequest>```
Success Response	Http Status: **200 Ok** Example : **Response** ```<HSSCheckResponse xmlns="http://era.nih.gov/hsct/HsctExternalService" xmlns:ns2="http://era.nih.gov/hsct/HsctCommonTypes-V1.0">
<passedValidation>true</passedValidation>
</HSSCheckResponse>```
Error Response	• Http Status: **403** ```{
"code": "403",
"message": "Service account does not have privileges for this operation. ErrorId : 1729880102787"
}``` • Http Status: **422** ```{
"code": "422",
"message": "Application ID 1104611289 does not exist. Error ID : 1729879888550"
}``` • Http Status: **500** ```{
"code": "500",
"message": " Error ID: 1729879961241 Could not unmarshal to [class gov.nih.era.hsct.hsctexternalservice.auto.HSSCheckRequest]: null; nested exception is javax.xml.bind.UnmarshalException\n - with linked exception:\n[org.xml.sax.SAXParseException; lineNumber: 2; columnNumber: 27; cvc-datatype-valid.1.2.1: '' is not a valid value for 'integer'.]"
}```

7.3 Input Values

After successful authentication into HSS ExternalService web service, the following field information applies:

HSSCheckRequest

#	Element Name	Description	Rule	Error when rule is not met	Error Code
1	applId	eRA application ID for which the HSS Check needs to be performed. For complex application with subprojects, a parent application ID must be password to performHSSCheck	Required	Http Status Error	N/A

Sample Request XML:

```
<hsc:HSSCheckRequest xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService">
 <hsc:applId>9997624</hsc:applId>
</hsc:HSSCheckRequest>
```

7.4 Output Values

The Web Service will return the following results:

Output Structure

HSSCheckResponse

#	Element Name	Description	XSD Complex Type Used
1	passedValidation	Indicates whether HSS Check passed or not	
2	responseMessage	Message indicating why the message is a success or failure	ResponseMessage of HsctCommonTypes.xsd

ResponseMessage

#	Element Name	Description
1	messageCode	Code of the message. It will be used to cross reference with the web service.
2	messageSeverity	Message severity. Valid values: Error, Warning
3	messageText	Message text

Sample Response XML:

```
<HSSCheckResponse xmlns:ns8="http://apply.grants.gov/system/GlobalLibrary-V2.0" xmlns:ns7="http://era.nih.gov
/hsct/HsctCommonTypes-V1.0" xmlns:ns6="http://era.nih.gov/hsct/HsctDelayedOnsetStudy-V1.0" xmlns:ns5="
http://era.nih.gov/hsct/HsctStudy-V3.0" xmlns:ns4="http://apply.grants.gov/system/Global-V1.0" xmlns:ns3="
http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns2="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-
V3.0" xmlns="http://era.nih.gov/hsct/HsctExternalService">
        <passedValidation>true</passedValidation>
</HSSCheckResponse>
```

```
<HSSCheckResponse xmlns:ns8="http://apply.grants.gov/system/GlobalLibrary-V2.0" xmlns:ns7="http://era.nih.gov
/hsct/HsctCommonTypes-V1.0" xmlns:ns6="http://era.nih.gov/hsct/HsctDelayedOnsetStudy-V1.0" xmlns:ns5="
http://era.nih.gov/hsct/HsctStudy-V3.0" xmlns:ns4="http://apply.grants.gov/system/Global-V1.0" xmlns:ns3="
http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns2="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-
V3.0" xmlns="http://era.nih.gov/hsct/HsctExternalService">
        <passedValidation>false</passedValidation>
        <messageList>
            <ns7:messageCode>ClinicalTrials.gov information does not match-266553</ns7:messageCode>
                    <ns7:messageSeverity>Error</ns7:messageSeverity>
            <ns7:messageText>Some of the Information provided in study "Decreasing the Temporal Window"
(Recruitment Status) does not match the information in Clinicaltrials.gov for the Clinicaltrials.gov identifier
provided "NCT04128761".Please contact the PO to address this issue with the recipient.</ns7:messageText>
        </messageList>
</HSSCheckResponse>
```

7.5 HSS Check Service : Errors/Warnings

	Message Codes	Result
1	Study attached to the parent project	***Warning Message:*** "Study <Study#,Study#> is attached to the parent project. Please contact the PO and/or other IC staff to transfer study to a subproject record."
2	Planned counts are required	***Warning message:*** "Planned counts are required to be greater than zero for Inclusion Enrollment Reports <IER#, IER#> under Study<Study#>, Inclusion Enrollment Reports<IER#,IER#> under Study <Study #>. Please contact the PO and/or IC inclusion staff to address this issue with the recipient"
3	IERs are required	***Error message:*** "At least one Inclusion Enrollment Report is required on Study <Study#> when Inclusion Monitoring is required for the study. Please contact the PO and/or IC inclusion staff to address this issue with the recipient"
4	ClinicalTrials.gov information does not match	***Warning message:*** "Some of the Information provided in study<study title> (list of elements that do not match) does not match the information in ClinicalTrials.gov for the ClinicalTrials.gov identifier provided <NCT #>.Please contact the PO to address this issue with the recipient."
5	ClinicalTrials.gov is down	***Warning message:*** "Link to Clinicaltrials.gov could not be established at this time to verify the consistency of the studies due to the service being unavailable."
6	NCT# missing	***Warning message:*** "Enrollment for <study title> has begun but no Clinicaltrials.gov Identification Number (NCT) has been provided. Please verify Clinicaltrials.gov registration compliance prior to award."
7	Results not reported to ClinicalTrials.gov	***~~Warning~~ Error message:*** The study <study title> Primary Completion date is more than 12 months in the past and results have not been submitted to ClinicalTrials.gov nor does an approved extension to submit the results on a later date exist. Please verify Clinicaltrials.gov results reporting compliance prior to award
8	Discrepant CT codes	***Warning message:*** ***When project-level CT code is No:*** "The CT code for project <project number> is No; however, Study <study#, study#> has a CT code of Yes. Please verify that the project level CT code reflects the CT code of the study records. ***When project-level CT code is Yes:*** All of the study records for <project number> have a CT code of No. However, the project level CT code is Yes. Please verify that the project level CT code reflects the CT code of the study records.

9	Possible Exemption 5 at Study	**Warning Message:** Study(ies)<Study ID, Study title> have been marked as Exemption 5 and do not have an approved 'Possible Exemption 5 policy request. Please contact the PO to submit a policy request in HSS for this study.
10	Possible Exemption 5 at application	**Warning message:** Project has been marked as Exemption 5 and no study(ies) have an approved 'Possible Exemption 5' Policy request. Please contact the PO to submit a policy request in HSS for this project.
11.	Data Issue	**Error Message:** A data issue has occurred. You must contact eRA helpdesk to fix it.
12.	Submission of individual level data	**Warning Message:** Participant-level inclusion data, including age at enrollment, is required for IER <IER ID> in Study <study ID>. Please contact the PO and/or IC inclusion staff to address this issue with the recipient.
13.	Discrepant Phase III values	**Warning Message:** The NIH-defined Phase 3 code for project <project number> is No; however, Study <study#, study#> includes the answer "Yes" to the question "Is this an NIH-defined Phase III clinical trial?" in Section 4 of the PHS Human Subjects and Clinical Trials Information Form. Please verify that the project level NIH-defined Phase 3 code reflects the NIH-defined Phase 3 information included in the study records.
14.	Discrepant Phase III values	**Warning Message:** *All of the study records for <project number> include a "No" answer to the question "Is this an NIH-defined Phase III clinical trial?" in Section 4 of the PHS Human Subjects and Clinical Trials Information Form. However, the project level NIH-defined Phase 3 code is Yes. Please verify that the project level NIH-defined Phase 3 code reflects the NIH-defined Phase 3 information included in the study records.*
15.	Discrepant Phase III values	**Warning Message:** The project level NIH-defined Phase 3 code is Yes. However, no study records exist. Please verify that the project level NIH-defined Phase 3 code is correct and request the recipient create a study record if necessary.
16	NCT# missing	**Error Message** Enrollment of first participant for <Study Title> was **more than 30 days,** but a Clincialtrials.gov identifier (NCT) has not been provided. Please complete Clinicaltrials.gov registration and use the Human Subjects link in G.4 to add the NCT number in the Human Subjects and Clinical Trial Information Form item 1.5."

8. XSDs

Non-prod Enviroment:

https://services.internal.test.era.nih.gov/hsct/services/hsctexternalservice?xsd=HsctExternalService.xsd

https://services.internal.test.era.nih.gov/hsct/services/hsctexternalservice?xsd=../hsctprocessor/HsctStudy-V3.0.xsd

https://services.internal.test.era.nih.gov/hsct/services/hsctexternalservice?xsd=../hsctprocessor/HsctDelayedOnsetStudy-V1.0.xsd

https://services.internal.stage.era.nih.gov/hsct/services/hsctexternalservice?xsd=HsctExternalService.xsd

https://services.internal.stage.era.nih.gov/hsct/services/hsctexternalservice?xsd=../hsctprocessor/HsctStudy-V3.0.xsd

https://services.internal.stage.era.nih.gov/hsct/services/hsctexternalservice?xsd=../hsctprocessor/HsctDelayedOnsetStudy-V1.0.xsd

Prod Environment :

https://services.internal.era.nih.gov/hsct/services/hsctexternalservice?xsd=HsctExternalService.xsd

https://services.internal.era.nih.gov/hsct/services/hsctexternalservice?xsd=../hsctprocessor/HsctStudy-V3.0.xsd

https://services.internal.era.nih.gov/hsct/services/hsctexternalservice?xsd=../hsctprocessor/HsctDelayedOnsetStudy-V1.0.xsd

8.1 Sample submitExternalData REST xml request

```
<hsc:SubmitExternalDataRequest xmlns:att="http://apply.grants.gov/system/Attachments-V1.0" xmlns:glob="
http://apply.grants.gov/system/Global-V1.0" xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService" xmlns:hsc2="
http://era.nih.gov/hsct/hsctDelayedOnsetStudy-V1.0" xmlns:ns1="http://apply.grants.gov/forms
/HumanSubjectStudy_3_0-V3.0" xmlns:ns4="http://era.nih.gov/hsct/HsctStudy-V3.0">
          <hsc:applicationsListWithStudies>
             <hsc:applicationHeaderInfo>
                <hsc:eraApplicationId>9947901</hsc:eraApplicationId>
                <hsc:refreshClinicalTrials>Y</hsc:refreshClinicalTrials>
             </hsc:applicationHeaderInfo>
                        <ns4:HsctStudy xmlns:ns1="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0"
xmlns:ns2="http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns3="http://apply.grants.gov/system/Global-V1.
0" xmlns:ns4="http://era.nih.gov/hsct/HsctStudy-V3.0">
                           <ns1:HumanSubjectStudy_3_0 ns1:FormVersion="3.0">
                                 <ns1:Study_id>-1</ns1:Study_id>
                                 <ns1:StudyTitle>New study via S2S 5132020</ns1:StudyTitle>
                                 <ns1:ExemptFedReg>Y: Yes</ns1:ExemptFedReg>
                                 <ns1:ExemptionNumbers>
                                   <ns1:ExemptionNumber>E1</ns1:ExemptionNumber>
                                   <ns1:ExemptionNumber>E2</ns1:ExemptionNumber>
                                 </ns1:ExemptionNumbers>
                                 <ns1:ClinicalTrialQuestionnaire>
                                   <ns1:HumanSubjectsIndicator>Y: Yes</ns1:HumanSubjectsIndicator>
                                   <ns1:InterventionAssigned>Y: Yes</ns1:InterventionAssigned>
                                   <ns1:EvaluateIntervention>Y: Yes</ns1:EvaluateIntervention>
                                   <ns1:HealthRelatedOutcome>Y: Yes</ns1:HealthRelatedOutcome>
                                 </ns1:ClinicalTrialQuestionnaire>
                                 <ns1:ClinicalTrialsIdentifier>NCT03827460</ns1:ClinicalTrialsIdentifier>
                                 <ns1:StudyPopulationCharacteristics>
                                   <ns1:StudyConditions>Fever</ns1:StudyConditions>
                                   <ns1:StudyConditions>Malaria</ns1:StudyConditions>
                                   <ns1:StudyConditions>Diagnosis</ns1:StudyConditions>
                                   <ns1:StudyConditions>Referral</ns1:StudyConditions>
                                   <ns1:EligibilityCriteria>Inclusion Criteria:

                                           - Patients with fever

                                           - uncomplicted malaria

                                          Exclusion Criteria:

                                           - Complicated malaria

                                           - known allergic reactions to Lumartem</ns1:EligibilityCriteria>
                                   <ns1:AgeLimits>
                                          <ns1:MinimumAge>
                                            <ns1:Age>1</ns1:Age>
                                            <ns1:AgeType>Months</ns1:AgeType>
                                          </ns1:MinimumAge>
                                          <ns1:MaximumAge>
                                            <ns1:Age>71</ns1:Age>
                                            <ns1:AgeType>Years</ns1:AgeType>
                                          </ns1:MaximumAge>
                                   </ns1:AgeLimits>
                                        <ns1:InclusionOfWomenAndMinorities>
                                        <ns1:attFile>
                                        <ns2:FileName>ASSIST_CT_Study1Appendix3_OV.pdf</ns2:FileName>
                                        <ns2:MimeType>application/pdf</ns2:MimeType>
                                        <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532130/HSCTA"/>
                                           <ns3:HashValue ns3:hashAlgorithm="SHA-1">+wldJvNoLIZxKueCkjb4u0+Jhf8=<
/ns3:HashValue>
                                        </ns1:attFile>
                                     </ns1:InclusionOfWomenAndMinorities>
                                     <ns1:RecruitmentAndRetentionPlan>
                                          <ns1:attFile>
                                            <ns2:FileName>CT_StdyTmln2_AD.pdf</ns2:FileName>
                                            <ns2:MimeType>application/pdf</ns2:MimeType>
                                            <ns2:FileLocation ns2:href="era://document/docservice/dataservices
```

/document/keyId/532131/HSCTA"/>
                                        <ns3:HashValue ns3:hashAlgorithm="SHA-1">qpoDFCEd5lx0a2EhohU7QxSmi2w=<
/ns3:HashValue>
                                    </ns1:attFile>
                            </ns1:RecruitmentAndRetentionPlan>
                            <ns1:RecruitmentStatus>Completed</ns1:RecruitmentStatus>
                            <ns1:StudyTimeline>
                                    <ns1:attFile>
                                        <ns2:FileName>ASSIST_CT_Inclusion_of_Individ_Across_Lifespan.pdf</ns2:
FileName>
                                        <ns2:MimeType>application/pdf</ns2:MimeType>
                                        <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532132/HSCTA"/>
                                        <ns3:HashValue ns3:hashAlgorithm="SHA-1">f03n6KRNpYqQJ1mvcMjPPjM8eVY=<
/ns3:HashValue>
                                    </ns1:attFile>
                            </ns1:StudyTimeline>
                            <ns1:FirstSubjectEnrollment>
                                    <ns1:EnrollmentDate>2010-09-01</ns1:EnrollmentDate>
                                    <ns1:AnticipatedActual>Actual</ns1:AnticipatedActual>
                            </ns1:FirstSubjectEnrollment>
                            <ns1:InclusionEnrollmentReport>
                                    <ns1:IER_id>-1</ns1:IER_id>
                            <ns1:InclusionEnrollmentReportTitle>New title Some of 5</ns1:
InclusionEnrollmentReportTitle>
                                    <ns1:ExistingDatasetOrResource>N: No</ns1:ExistingDatasetOrResource>
                                    <ns1:EnrollmentLocationType>Domestic</ns1:EnrollmentLocationType>
                                    <ns1:EnrollmentCountry>USA: UNITED STATES</ns1:EnrollmentCountry>
                                    <ns1:EnrollmentLocations>Denmark</ns1:EnrollmentLocations>
                                    <ns1:Planned>
                                      <ns1:NotHispanic>
                                            <ns1:Female>
                                              <ns1:AmericanIndian>1</ns1:AmericanIndian>
                                              <ns1:Asian>2</ns1:Asian>
                                              <ns1:Hawaiian>0</ns1:Hawaiian>
                                              <ns1:Black>0</ns1:Black>
                                              <ns1:White>0</ns1:White>
                                              <ns1:MultipleRace>0</ns1:MultipleRace>
                                              <ns1:Total>3</ns1:Total>
                                            </ns1:Female>
                                            <ns1:Male>
                                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                              <ns1:Asian>0</ns1:Asian>
                                              <ns1:Hawaiian>0</ns1:Hawaiian>
                                              <ns1:Black>4564</ns1:Black>
                                              <ns1:White>0</ns1:White>
                                              <ns1:MultipleRace>0</ns1:MultipleRace>
                                              <ns1:Total>0</ns1:Total>
                                            </ns1:Male>
                                      </ns1:NotHispanic>
                                      <ns1:Hispanic>
                                            <ns1:Female>
                                              <ns1:AmericanIndian>2</ns1:AmericanIndian>
                                              <ns1:Asian>2637</ns1:Asian>
                                              <ns1:Hawaiian>0</ns1:Hawaiian>
                                              <ns1:Black>0</ns1:Black>
                                              <ns1:White>66</ns1:White>
                                              <ns1:MultipleRace>0</ns1:MultipleRace>
                                              <ns1:Total>70</ns1:Total>
                                            </ns1:Female>
                                            <ns1:Male>
                                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                              <ns1:Asian>0</ns1:Asian>
                                              <ns1:Hawaiian>0</ns1:Hawaiian>
                                              <ns1:Black>0</ns1:Black>
                                              <ns1:White>0</ns1:White>
                                              <ns1:MultipleRace>0</ns1:MultipleRace>
                                              <ns1:Total>0</ns1:Total>
                                            </ns1:Male>
                                      </ns1:Hispanic>
                                      <ns1:Total>

```xml
                                        <ns1:AmericanIndian>3</ns1:AmericanIndian>
                                        <ns1:Asian>4</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>66</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:Total>73</ns1:Total>
                            </ns1:Total>
                        </ns1:Planned>
                        <ns1:Cumulative>
                            <ns1:NotHispanic>
                                    <ns1:Female>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Female>
                                    <ns1:Male>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Male>
                                    <ns1:UnknownGender>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:UnknownGender>
                            </ns1:NotHispanic>
                            <ns1:Hispanic>
                                    <ns1:Female>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Female>
                                    <ns1:Male>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Male>
                                    <ns1:UnknownGender>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
```

```xml
                                                    <ns1:Total>0</ns1:Total>
                                                </ns1:UnknownGender>
                                        </ns1:Hispanic>
                                        <ns1:UnknownEthnicity>
                                                <ns1:Female>
                                                  <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                                  <ns1:Asian>0</ns1:Asian>
                                                  <ns1:Hawaiian>0</ns1:Hawaiian>
                                                  <ns1:Black>0</ns1:Black>
                                                  <ns1:White>0</ns1:White>
                                                  <ns1:MultipleRace>0</ns1:MultipleRace>
                                                  <ns1:UnknownRace>0</ns1:UnknownRace>
                                                  <ns1:Total>0</ns1:Total>
                                                </ns1:Female>
                                                <ns1:Male>
                                                  <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                                  <ns1:Asian>0</ns1:Asian>
                                                  <ns1:Hawaiian>0</ns1:Hawaiian>
                                                  <ns1:Black>0</ns1:Black>
                                                  <ns1:White>0</ns1:White>
                                                  <ns1:MultipleRace>0</ns1:MultipleRace>
                                                  <ns1:UnknownRace>0</ns1:UnknownRace>
                                                  <ns1:Total>0</ns1:Total>
                                                </ns1:Male>
                                                <ns1:UnknownGender>
                                                  <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                                  <ns1:Asian>0</ns1:Asian>
                                                  <ns1:Hawaiian>0</ns1:Hawaiian>
                                                  <ns1:Black>0</ns1:Black>
                                                  <ns1:White>0</ns1:White>
                                                  <ns1:MultipleRace>0</ns1:MultipleRace>
                                                  <ns1:UnknownRace>0</ns1:UnknownRace>
                                                  <ns1:Total>0</ns1:Total>
                                                </ns1:UnknownGender>
                                        </ns1:UnknownEthnicity>
                                        <ns1:Total>
                                                <ns1:AmericanIndian>10</ns1:AmericanIndian>
                                                <ns1:Asian>20</ns1:Asian>
                                                <ns1:Hawaiian>0</ns1:Hawaiian>
                                                <ns1:Black>30</ns1:Black>
                                                <ns1:White>77</ns1:White>
                                                <ns1:MultipleRace>89</ns1:MultipleRace>
                                                <ns1:UnknownRace>0</ns1:UnknownRace>
                                                <ns1:Total>0</ns1:Total>
                                        </ns1:Total>
                                </ns1:Cumulative>
                        </ns1:InclusionEnrollmentReport>
                </ns1:StudyPopulationCharacteristics>
                <ns1:ProtectionMonitoringPlans>
                  <ns1:ProtectionOfHumanSubjects>
                        <ns1:attFile>
                          <ns2:FileName>ASSIST_CT_PrtctofHmnSbjct4.pdf</ns2:FileName>
                          <ns2:MimeType>application/pdf</ns2:MimeType>
                          <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532134/HSCTA"/>
                          <ns3:HashValue ns3:hashAlgorithm="SHA-1">iGEAZlVUtPXFe1b6L9mfMj0zKXw=<
/ns3:HashValue>
                        </ns1:attFile>
                  </ns1:ProtectionOfHumanSubjects>
                <ns1:MultiSiteStudy>N: No</ns1:MultiSiteStudy>
                <ns1:DataSafetyMonitoringPlan>
                        <ns1:attFile>
                          <ns2:FileName>ASSIST_CT_InclnWmnMnty_AD_2.pdf</ns2:FileName>
                          <ns2:MimeType>application/pdf</ns2:MimeType>
                          <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532135/HSCTA"/>
                          <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWMyG+xOj3Reiq0=<
/ns3:HashValue>
                        </ns1:attFile>
                </ns1:DataSafetyMonitoringPlan>
                <ns1:BoardAppointed>N: No</ns1:BoardAppointed>
```

```xml
                                    <ns1:StudyTeamStructure>
                                        <ns1:attFile>
                                            <ns2:FileName>ASSIST_CT_InclWmnMty_AMC1.pdf</ns2:FileName>
                                            <ns2:MimeType>application/pdf</ns2:MimeType>
                                            <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532136/HSCTA"/>
                                            <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWMyG+xOj3Reiq0=<
/ns3:HashValue>
                                        </ns1:attFile>
                                    </ns1:StudyTeamStructure>
                                </ns1:ProtectionMonitoringPlans>
                                <ns1:ProtocolSynopsis>
                                    <ns1:StudyDesign>
                                        <ns1:DetailedDescription>test design</ns1:DetailedDescription>
                                        <ns1:PrimaryPurpose>Diagnostics</ns1:PrimaryPurpose>
                                        <ns1:Interventions>
                                            <ns1:InterventionType>Device (including sham)</ns1:InterventionType>
                                            <ns1:InterventionName>Rapid diagnostic test</ns1:InterventionName>
                                            <ns1:InterventionDescription>Diagnosis of malaria using rapid
diagnostic test</ns1:InterventionDescription>
                                        </ns1:Interventions>
                                        <ns1:Interventions>
                                            <ns1:InterventionType>Drug (including placebo)</ns1:InterventionType>
                                            <ns1:InterventionName>Lumartem</ns1:InterventionName>
                                            <ns1:InterventionDescription>Presumptive treatment of malaria/fever<
/ns1:InterventionDescription>
                                        </ns1:Interventions>
                                        <ns1:StudyPhase>N/A</ns1:StudyPhase>
                                        <ns1:NIHPhase3ClinicalTrial>N: NO</ns1:NIHPhase3ClinicalTrial>
                                        <ns1:InterventionModel>Parallel</ns1:InterventionModel>
                                        <ns1:Masking>N: No</ns1:Masking>
                                        <ns1:MaskingType>
                                            <ns1:Participant>N: No</ns1:Participant>
                                            <ns1:CareProvider>N: No</ns1:CareProvider>
                                            <ns1:Investigator>N: No</ns1:Investigator>
                                            <ns1:OutcomesAssessor>N: No</ns1:OutcomesAssessor>
                                        </ns1:MaskingType>
                                        <ns1:Allocation>Randomized</ns1:Allocation>
                                    </ns1:StudyDesign>
                                    <ns1:OutcomesMeasures>
                                        <ns1:OutcomeName>Appropriateness of treatment</ns1:OutcomeName>
                                        <ns1:OutcomeType>Primary</ns1:OutcomeType>
                                        <ns1:TimeFrame>36 months</ns1:TimeFrame>
                                        <ns1:OutcomeDescription>test</ns1:OutcomeDescription>
                                    </ns1:OutcomesMeasures>
                                    <ns1:OutcomesMeasures>
                                        <ns1:OutcomeName>Appropriateness of referral of complicated malaria
cases</ns1:OutcomeName>
                                        <ns1:OutcomeType>Secondary</ns1:OutcomeType>
                                        <ns1:TimeFrame>36 months</ns1:TimeFrame>
                                        <ns1:OutcomeDescription>test1</ns1:OutcomeDescription>
                                    </ns1:OutcomesMeasures>
                                    <ns1:StatisticalDesignPower>
                                        <ns1:attFile>
                                            <ns2:FileName>ASSIST_CT_DOnsetStudy3.pdf</ns2:FileName>
                                            <ns2:MimeType>application/pdf</ns2:MimeType>
                                            <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532137/HSCTA"/>
                                            <ns3:HashValue ns3:hashAlgorithm="SHA-1">6P/GJW08dHsKQsPAkLREhW1sncA=<
/ns3:HashValue>
                                        </ns1:attFile>
                                    </ns1:StatisticalDesignPower>
                                    <ns1:SubjectParticipationDuration>1 month</ns1:SubjectParticipationDuration>
                                    <ns1:FDARegulatedIntervention>N: No</ns1:FDARegulatedIntervention>
                                    <ns1:ApplicableClinicalTrial>Y: Yes</ns1:ApplicableClinicalTrial>
                                    <ns1:DisseminationPlan>
                                        <ns1:attFile>
                                            <ns2:FileName>ASSIST_CT_DisseminPlan_AMC1.pdf</ns2:FileName>
                                            <ns2:MimeType>application/pdf</ns2:MimeType>
                                            <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532138/HSCTA"/>
```

                                                            <ns3:HashValue ns3:hashAlgorithm="SHA-1">Sw1aJewy3joxSijfLZ+7PHaS2HE=</ns3:HashValue>
                                                    </ns1:attFile>
                                            </ns1:DisseminationPlan>
                                        </ns1:ProtocolSynopsis>
                                </ns1:HumanSubjectStudy_3_0>
                                        <ns4:postSubmissionInfo>
                                        <ns4:seriousAdverseEvents>Y: Yes</ns4:seriousAdverseEvents>
                                        <ns4:moreFrequentAdverseEvents>N: No</ns4:moreFrequentAdverseEvents>
                                        <ns4:studyStartDate>
                                                <ns4:dateValue>2021-01-12-05:00</ns4:dateValue>
                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                        </ns4:studyStartDate>
                                        <ns4:studyPrimaryCompletionDate>
                                                <ns4:dateValue>2027-05-11-04:00</ns4:dateValue>
                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                        </ns4:studyPrimaryCompletionDate>
                                        <ns4:studyFinalCompletionDate>
                                                <ns4:dateValue>2027-08-11-04:00</ns4:dateValue>
                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                        </ns4:studyFinalCompletionDate>
                                        <ns4:enrollmentAndRandomization>
                                                <ns4:percent25RecruitedBy>
                                                        <ns4:dateValue>2027-01-13-05:00</ns4:dateValue>
                                                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                </ns4:percent25RecruitedBy>
                                                <ns4:percent50RecruitedBy>
                                                        <ns4:dateValue>2027-02-01-05:00</ns4:dateValue>
                                                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                </ns4:percent50RecruitedBy>
                                                <ns4:percent75RecruitedBy>
                                                        <ns4:dateValue>2027-03-01-05:00</ns4:dateValue>
                                                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                </ns4:percent75RecruitedBy>
                                                <ns4:percent100RecruitedBy>
                                                        <ns4:dateValue>2027-10-21-04:00</ns4:dateValue>
                                                        <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                </ns4:percent100RecruitedBy>
                                        </ns4:enrollmentAndRandomization>
                                        <ns4:completionOfPrimaryEndpointAnalysis>
                                                <ns4:dateValue>2027-06-01-04:00</ns4:dateValue>
                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                        </ns4:completionOfPrimaryEndpointAnalysis>
                                        <ns4:completionOfSecondaryEndpointAnalysis>
                                                <ns4:dateValue>2027-07-01-04:00</ns4:dateValue>
                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                        </ns4:completionOfSecondaryEndpointAnalysis>
                                        <ns4:reportingOfResults>
                                                <ns4:dateValue>2027-08-01-04:00</ns4:dateValue>
                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                        </ns4:reportingOfResults>

                                        <ns4:registrationAndReportingCertification>N: No</ns4:registrationAndReportingCertification>
                                </ns4:postSubmissionInfo>
                                <ns4:ierParticipantData>
                                        <ns4:ierId>-1</ns4:ierId>
                                         <ns4:participantDataAttachment>
                                                <ns2:FileName>ParticipantLevelData-Template.csv</ns2:FileName>
                                                <ns2:MimeType>text/csv</ns2:MimeType>
                                                <ns2:FileLocation ns2:href="era://document/docservice/dataservices/document/keyId/41507786/HSCTA"/>
                                                <ns3:HashValue ns3:hashAlgorithm="SHA-1">BAQOue13GPEeIyT+n6DsA4fASV5FY=</ns3:HashValue>
                                        </ns4:participantDataAttachment>
                                </ns4:ierParticipantData>
                                <!-- <ns4:sourceUniqueValue>743162E814C2154A8D65AF403C96BA13</ns4:

```
sourceUniqueValue>-->
                    </ns4:HsctStudy>

                    <!-- Zero or more repetitions -->
         <hsc2:HsctDelayedOnsetStudy>
                        <hsc2:studyId>123456</hsc2:studyId>
            <hsc2:studyTitle>Delayed Study Title</hsc2:studyTitle>
            <hsc2:anticipatedClinicalTrial>Y: Yes</hsc2:anticipatedClinicalTrial>
            <hsc2:justification>
               <hsc2:attFile>
                  <att:FileName>att:FileName</att:FileName>
                  <att:MimeType>att:MimeType</att:MimeType>
                  <att:FileLocation att:href="era://document/docservice/dataservices/document/keyId/532135
/HSCTA" />
                  <glob:HashValue glob:hashAlgorithm="">MA==</glob:HashValue>
               </hsc2:attFile>
            </hsc2:justification>
         </hsc2:HsctDelayedOnsetStudy>
      </hsc:applicationsListWithStudies>
            <hsc:applicationsListWithStudies>
         <hsc:applicationHeaderInfo>
            <hsc:eraApplicationId>9947902</hsc:eraApplicationId>
            <hsc:refreshClinicalTrials>Y</hsc:refreshClinicalTrials>
         </hsc:applicationHeaderInfo>
                    <ns4:HsctStudy xmlns:ns1="http://apply.grants.gov/forms/HumanSubjectStudy_3_0-V3.0"
xmlns:ns2="http://apply.grants.gov/system/Attachments-V1.0" xmlns:ns3="http://apply.grants.gov/system/Global-V1.
0" xmlns:ns4="http://era.nih.gov/hsct/HsctStudy-V3.0">
                    <ns1:HumanSubjectStudy_3_0 ns1:FormVersion="3.0">
                       <ns1:Study_id>123457</ns1:Study_id>
                       <ns1:StudyTitle>New study via S2S 5132020</ns1:StudyTitle>
                       <ns1:ExemptFedReg>Y: Yes</ns1:ExemptFedReg>
                       <ns1:ExemptionNumbers>
                         <ns1:ExemptionNumber>E1</ns1:ExemptionNumber>
                         <ns1:ExemptionNumber>E2</ns1:ExemptionNumber>
                       </ns1:ExemptionNumbers>
                       <ns1:ClinicalTrialQuestionnaire>
                         <ns1:HumanSubjectsIndicator>Y: Yes</ns1:HumanSubjectsIndicator>
                         <ns1:InterventionAssigned>Y: Yes</ns1:InterventionAssigned>
                         <ns1:EvaluateIntervention>Y: Yes</ns1:EvaluateIntervention>
                         <ns1:HealthRelatedOutcome>Y: Yes</ns1:HealthRelatedOutcome>
                       </ns1:ClinicalTrialQuestionnaire>
                       <ns1:ClinicalTrialsIdentifier>NCT03827460</ns1:ClinicalTrialsIdentifier>
                       <ns1:StudyPopulationCharacteristics>
                         <ns1:StudyConditions>Fever</ns1:StudyConditions>
                         <ns1:StudyConditions>Malaria</ns1:StudyConditions>
                         <ns1:StudyConditions>Diagnosis</ns1:StudyConditions>
                         <ns1:StudyConditions>Referral</ns1:StudyConditions>
                         <ns1:EligibilityCriteria>Inclusion Criteria:

                               - Patients with fever

                               - uncomplicted malaria

                              Exclusion Criteria:

                               - Complicated malaria

                               - known allergic reactions to Lumartem</ns1:EligibilityCriteria>
                         <ns1:AgeLimits>
                              <ns1:MinimumAge>
                                <ns1:Age>1</ns1:Age>
                                <ns1:AgeType>Months</ns1:AgeType>
                              </ns1:MinimumAge>
                              <ns1:MaximumAge>
                                <ns1:Age>71</ns1:Age>
                                <ns1:AgeType>Years</ns1:AgeType>
                              </ns1:MaximumAge>
                         </ns1:AgeLimits>
                              <ns1:InclusionOfWomenAndMinorities>
                         <ns1:attFile>
                            <ns2:FileName>ASSIST_CT_Study1Appendix3_OV.pdf</ns2:FileName>
```

                                        <ns2:MimeType>application/pdf</ns2:MimeType>
                                        <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532130/HSCTA"/>
                                        <ns3:HashValue ns3:hashAlgorithm="SHA-1">+wldJvNoLIZxKueCkjb4u0+Jhf8=<
/ns3:HashValue>
                                </ns1:attFile>
                        </ns1:InclusionOfWomenAndMinorities>
                        <ns1:RecruitmentAndRetentionPlan>
                                <ns1:attFile>
                                        <ns2:FileName>CT_StdyTmln2_AD.pdf</ns2:FileName>
                                        <ns2:MimeType>application/pdf</ns2:MimeType>
                                        <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532131/HSCTA"/>
                                        <ns3:HashValue ns3:hashAlgorithm="SHA-1">qpoDFCEd5lx0a2EhohU7QxSmi2w=<
/ns3:HashValue>
                                </ns1:attFile>
                        </ns1:RecruitmentAndRetentionPlan>
                        <ns1:RecruitmentStatus>Completed</ns1:RecruitmentStatus>
                        <ns1:StudyTimeline>
                                <ns1:attFile>
                                        <ns2:FileName>ASSIST_CT_Inclusion_of_Individ_Across_Lifespan.pdf</ns2:
FileName>
                                        <ns2:MimeType>application/pdf</ns2:MimeType>
                                        <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532132/HSCTA"/>
                                        <ns3:HashValue ns3:hashAlgorithm="SHA-1">f03n6KRNpYqQJ1mvcMjPPjM8eVY=<
/ns3:HashValue>
                                </ns1:attFile>
                        </ns1:StudyTimeline>
                        <ns1:FirstSubjectEnrollment>
                                <ns1:EnrollmentDate>2010-09-01</ns1:EnrollmentDate>
                                <ns1:AnticipatedActual>Actual</ns1:AnticipatedActual>
                        </ns1:FirstSubjectEnrollment>
                        <ns1:InclusionEnrollmentReport>
                                <ns1:IER_id>-1</ns1:IER_id>
                        <ns1:InclusionEnrollmentReportTitle>New title Some of 5</ns1:
InclusionEnrollmentReportTitle>
                                <ns1:ExistingDatasetOrResource>N: No</ns1:ExistingDatasetOrResource>
                                <ns1:EnrollmentLocationType>Domestic</ns1:EnrollmentLocationType>
                                <ns1:EnrollmentCountry>USA: UNITED STATES</ns1:EnrollmentCountry>
                                <ns1:EnrollmentLocations>Denmark</ns1:EnrollmentLocations>
                                <ns1:Planned>
                                   <ns1:NotHispanic>
                                         <ns1:Female>
                                            <ns1:AmericanIndian>1</ns1:AmericanIndian>
                                            <ns1:Asian>2</ns1:Asian>
                                            <ns1:Hawaiian>0</ns1:Hawaiian>
                                            <ns1:Black>0</ns1:Black>
                                            <ns1:White>0</ns1:White>
                                            <ns1:MultipleRace>0</ns1:MultipleRace>
                                            <ns1:Total>3</ns1:Total>
                                         </ns1:Female>
                                         <ns1:Male>
                                            <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                            <ns1:Asian>0</ns1:Asian>
                                            <ns1:Hawaiian>0</ns1:Hawaiian>
                                            <ns1:Black>4564</ns1:Black>
                                            <ns1:White>0</ns1:White>
                                            <ns1:MultipleRace>0</ns1:MultipleRace>
                                            <ns1:Total>0</ns1:Total>
                                         </ns1:Male>
                                   </ns1:NotHispanic>
                                   <ns1:Hispanic>
                                         <ns1:Female>
                                            <ns1:AmericanIndian>2</ns1:AmericanIndian>
                                            <ns1:Asian>2637</ns1:Asian>
                                            <ns1:Hawaiian>0</ns1:Hawaiian>
                                            <ns1:Black>0</ns1:Black>
                                            <ns1:White>66</ns1:White>
                                            <ns1:MultipleRace>0</ns1:MultipleRace>
                                            <ns1:Total>70</ns1:Total>

```xml
                                  </ns1:Female>
                                  <ns1:Male>
                                    <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                    <ns1:Asian>0</ns1:Asian>
                                    <ns1:Hawaiian>0</ns1:Hawaiian>
                                    <ns1:Black>0</ns1:Black>
                                    <ns1:White>0</ns1:White>
                                    <ns1:MultipleRace>0</ns1:MultipleRace>
                                    <ns1:Total>0</ns1:Total>
                                  </ns1:Male>
                          </ns1:Hispanic>
                          <ns1:Total>
                                    <ns1:AmericanIndian>3</ns1:AmericanIndian>
                                    <ns1:Asian>4</ns1:Asian>
                                    <ns1:Hawaiian>0</ns1:Hawaiian>
                                    <ns1:Black>0</ns1:Black>
                                    <ns1:White>66</ns1:White>
                                    <ns1:MultipleRace>0</ns1:MultipleRace>
                                    <ns1:Total>73</ns1:Total>
                          </ns1:Total>
                  </ns1:Planned>
                  <ns1:Cumulative>
                    <ns1:NotHispanic>
                            <ns1:Female>
                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                              <ns1:Asian>0</ns1:Asian>
                              <ns1:Hawaiian>0</ns1:Hawaiian>
                              <ns1:Black>0</ns1:Black>
                              <ns1:White>0</ns1:White>
                              <ns1:MultipleRace>0</ns1:MultipleRace>
                              <ns1:UnknownRace>0</ns1:UnknownRace>
                              <ns1:Total>0</ns1:Total>
                            </ns1:Female>
                            <ns1:Male>
                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                              <ns1:Asian>0</ns1:Asian>
                              <ns1:Hawaiian>0</ns1:Hawaiian>
                              <ns1:Black>0</ns1:Black>
                              <ns1:White>0</ns1:White>
                              <ns1:MultipleRace>0</ns1:MultipleRace>
                              <ns1:UnknownRace>0</ns1:UnknownRace>
                              <ns1:Total>0</ns1:Total>
                            </ns1:Male>
                            <ns1:UnknownGender>
                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                              <ns1:Asian>0</ns1:Asian>
                              <ns1:Hawaiian>0</ns1:Hawaiian>
                              <ns1:Black>0</ns1:Black>
                              <ns1:White>0</ns1:White>
                              <ns1:MultipleRace>0</ns1:MultipleRace>
                              <ns1:UnknownRace>0</ns1:UnknownRace>
                              <ns1:Total>0</ns1:Total>
                            </ns1:UnknownGender>
                    </ns1:NotHispanic>
                    <ns1:Hispanic>
                            <ns1:Female>
                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                              <ns1:Asian>0</ns1:Asian>
                              <ns1:Hawaiian>0</ns1:Hawaiian>
                              <ns1:Black>0</ns1:Black>
                              <ns1:White>0</ns1:White>
                              <ns1:MultipleRace>0</ns1:MultipleRace>
                              <ns1:UnknownRace>0</ns1:UnknownRace>
                              <ns1:Total>0</ns1:Total>
                            </ns1:Female>
                            <ns1:Male>
                              <ns1:AmericanIndian>0</ns1:AmericanIndian>
                              <ns1:Asian>0</ns1:Asian>
                              <ns1:Hawaiian>0</ns1:Hawaiian>
                              <ns1:Black>0</ns1:Black>
                              <ns1:White>0</ns1:White>
```

```xml
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Male>
                                    <ns1:UnknownGender>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:UnknownGender>
                                </ns1:Hispanic>
                                <ns1:UnknownEthnicity>
                                    <ns1:Female>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Female>
                                    <ns1:Male>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:Male>
                                    <ns1:UnknownGender>
                                        <ns1:AmericanIndian>0</ns1:AmericanIndian>
                                        <ns1:Asian>0</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>0</ns1:Black>
                                        <ns1:White>0</ns1:White>
                                        <ns1:MultipleRace>0</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                    </ns1:UnknownGender>
                                </ns1:UnknownEthnicity>
                                <ns1:Total>
                                        <ns1:AmericanIndian>10</ns1:AmericanIndian>
                                        <ns1:Asian>20</ns1:Asian>
                                        <ns1:Hawaiian>0</ns1:Hawaiian>
                                        <ns1:Black>30</ns1:Black>
                                        <ns1:White>77</ns1:White>
                                        <ns1:MultipleRace>89</ns1:MultipleRace>
                                        <ns1:UnknownRace>0</ns1:UnknownRace>
                                        <ns1:Total>0</ns1:Total>
                                </ns1:Total>
                            </ns1:Cumulative>
                        </ns1:InclusionEnrollmentReport>
                    </ns1:StudyPopulationCharacteristics>
                    <ns1:ProtectionMonitoringPlans>
                        <ns1:ProtectionOfHumanSubjects>
                            <ns1:attFile>
                                <ns2:FileName>ASSIST_CT_PrtctofHmnSbjct4.pdf</ns2:FileName>
                                <ns2:MimeType>application/pdf</ns2:MimeType>
                                <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532134/HSCTA"/>
                                <ns3:HashValue ns3:hashAlgorithm="SHA-1">iGEAZlVUtPXFe1b6L9mfMj0zKXw=<
/ns3:HashValue>
                            </ns1:attFile>
                        </ns1:ProtectionOfHumanSubjects>
```

```xml
                                        <ns1:MultiSiteStudy>N: No</ns1:MultiSiteStudy>
                                        <ns1:DataSafetyMonitoringPlan>
                                              <ns1:attFile>
                                                <ns2:FileName>ASSIST_CT_InclnWmnMnty_AD_2.pdf</ns2:FileName>
                                                <ns2:MimeType>application/pdf</ns2:MimeType>
                                                <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532135/HSCTA"/>
                                                <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWMyG+xOj3Reiq0=<
/ns3:HashValue>
                                              </ns1:attFile>
                                        </ns1:DataSafetyMonitoringPlan>
                                        <ns1:BoardAppointed>N: No</ns1:BoardAppointed>
                                        <ns1:StudyTeamStructure>
                                              <ns1:attFile>
                                                <ns2:FileName>ASSIST_CT_InclWmnMty_AMC1.pdf</ns2:FileName>
                                                <ns2:MimeType>application/pdf</ns2:MimeType>
                                                <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532136/HSCTA"/>
                                                <ns3:HashValue ns3:hashAlgorithm="SHA-1">m1/tAhslsTvjxWMyG+xOj3Reiq0=<
/ns3:HashValue>
                                              </ns1:attFile>
                                        </ns1:StudyTeamStructure>
                                  </ns1:ProtectionMonitoringPlans>
                                  <ns1:ProtocolSynopsis>
                                    <ns1:StudyDesign>
                                        <ns1:DetailedDescription>test design</ns1:DetailedDescription>
                                        <ns1:PrimaryPurpose>Diagnostics</ns1:PrimaryPurpose>
                                        <ns1:Interventions>
                                          <ns1:InterventionType>Device (including sham)</ns1:InterventionType>
                                          <ns1:InterventionName>Rapid diagnostic test</ns1:InterventionName>
                                          <ns1:InterventionDescription>Diagnosis of malaria using rapid
diagnostic test</ns1:InterventionDescription>
                                        </ns1:Interventions>
                                        <ns1:Interventions>
                                          <ns1:InterventionType>Drug (including placebo)</ns1:InterventionType>
                                          <ns1:InterventionName>Lumartem</ns1:InterventionName>
                                          <ns1:InterventionDescription>Presumptive treatment of malaria/fever<
/ns1:InterventionDescription>
                                        </ns1:Interventions>
                                        <ns1:StudyPhase>N/A</ns1:StudyPhase>
                                        <ns1:NIHPhase3ClinicalTrial>N: NO</ns1:NIHPhase3ClinicalTrial>
                                        <ns1:InterventionModel>Parallel</ns1:InterventionModel>
                                        <ns1:Masking>N: No</ns1:Masking>
                                        <ns1:MaskingType>
                                          <ns1:Participant>N: No</ns1:Participant>
                                          <ns1:CareProvider>N: No</ns1:CareProvider>
                                          <ns1:Investigator>N: No</ns1:Investigator>
                                          <ns1:OutcomesAssessor>N: No</ns1:OutcomesAssessor>
                                        </ns1:MaskingType>
                                        <ns1:Allocation>Randomized</ns1:Allocation>
                                    </ns1:StudyDesign>
                                    <ns1:OutcomesMeasures>
                                        <ns1:OutcomeName>Appropriateness of treatment</ns1:OutcomeName>
                                        <ns1:OutcomeType>Primary</ns1:OutcomeType>
                                        <ns1:TimeFrame>36 months</ns1:TimeFrame>
                                        <ns1:OutcomeDescription>test</ns1:OutcomeDescription>
                                    </ns1:OutcomesMeasures>
                                    <ns1:OutcomesMeasures>
                                        <ns1:OutcomeName>Appropriateness of referral of complicated malaria
cases</ns1:OutcomeName>
                                        <ns1:OutcomeType>Secondary</ns1:OutcomeType>
                                        <ns1:TimeFrame>36 months</ns1:TimeFrame>
                                        <ns1:OutcomeDescription>test1</ns1:OutcomeDescription>
                                    </ns1:OutcomesMeasures>
                                    <ns1:StatisticalDesignPower>
                                        <ns1:attFile>
                                          <ns2:FileName>ASSIST_CT_DOnsetStudy3.pdf</ns2:FileName>
                                          <ns2:MimeType>application/pdf</ns2:MimeType>
                                          <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532137/HSCTA"/>
                                          <ns3:HashValue ns3:hashAlgorithm="SHA-1">6P/GJW08dHsKQsPAkLREhW1sncA=<
```

                                    /ns3:HashValue>
                                                                </ns1:attFile>
                                                        </ns1:StatisticalDesignPower>
                                                        <ns1:SubjectParticipationDuration>1 month</ns1:SubjectParticipationDuration>
                                                        <ns1:FDARegulatedIntervention>N: No</ns1:FDARegulatedIntervention>
                                                        <ns1:ApplicableClinicalTrial>Y: Yes</ns1:ApplicableClinicalTrial>
                                                        <ns1:DisseminationPlan>
                                                                <ns1:attFile>
                                                                  <ns2:FileName>ASSIST_CT_DisseminPlan_AMC1.pdf</ns2:FileName>
                                                                  <ns2:MimeType>application/pdf</ns2:MimeType>
                                                                  <ns2:FileLocation ns2:href="era://document/docservice/dataservices
/document/keyId/532138/HSCTA"/>
                                                                  <ns3:HashValue ns3:hashAlgorithm="SHA-1">Sw1aJewy3joxSijfLZ+7PHaS2HE=<
/ns3:HashValue>
                                                                </ns1:attFile>
                                                        </ns1:DisseminationPlan>
                                                </ns1:ProtocolSynopsis>
                                        </ns1:HumanSubjectStudy_3_0>
                                                        <ns4:postSubmissionInfo>
                                                        <ns4:seriousAdverseEvents>Y: Yes</ns4:seriousAdverseEvents>
                                                        <ns4:moreFrequentAdverseEvents>N: No</ns4:moreFrequentAdverseEvents>
                                                        <ns4:studyStartDate>
                                                                <ns4:dateValue>2021-01-12-05:00</ns4:dateValue>
                                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                        </ns4:studyStartDate>
                                                        <ns4:studyPrimaryCompletionDate>
                                                                <ns4:dateValue>2027-05-11-04:00</ns4:dateValue>
                                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                        </ns4:studyPrimaryCompletionDate>
                                                        <ns4:studyFinalCompletionDate>
                                                                <ns4:dateValue>2027-08-11-04:00</ns4:dateValue>
                                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                        </ns4:studyFinalCompletionDate>
                                                        <ns4:enrollmentAndRandomization>
                                                                <ns4:percent25RecruitedBy>
                                                                        <ns4:dateValue>2027-01-13-05:00</ns4:dateValue>
                                                                        <ns4:anticipatedActual>Anticipated</ns4:
anticipatedActual>
                                                                </ns4:percent25RecruitedBy>
                                                                <ns4:percent50RecruitedBy>
                                                                        <ns4:dateValue>2027-02-01-05:00</ns4:dateValue>
                                                                        <ns4:anticipatedActual>Anticipated</ns4:
anticipatedActual>
                                                                </ns4:percent50RecruitedBy>
                                                                <ns4:percent75RecruitedBy>
                                                                        <ns4:dateValue>2027-03-01-05:00</ns4:dateValue>
                                                                        <ns4:anticipatedActual>Anticipated</ns4:
anticipatedActual>
                                                                </ns4:percent75RecruitedBy>
                                                                <ns4:percent100RecruitedBy>
                                                                        <ns4:dateValue>2027-10-21-04:00</ns4:dateValue>
                                                                        <ns4:anticipatedActual>Anticipated</ns4:
anticipatedActual>
                                                                </ns4:percent100RecruitedBy>
                                                        </ns4:enrollmentAndRandomization>
                                                        <ns4:completionOfPrimaryEndpointAnalysis>
                                                                <ns4:dateValue>2027-06-01-04:00</ns4:dateValue>
                                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                        </ns4:completionOfPrimaryEndpointAnalysis>
                                                        <ns4:completionOfSecondaryEndpointAnalysis>
                                                                <ns4:dateValue>2027-07-01-04:00</ns4:dateValue>
                                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                        </ns4:completionOfSecondaryEndpointAnalysis>
                                                        <ns4:reportingOfResults>
                                                                <ns4:dateValue>2027-08-01-04:00</ns4:dateValue>
                                                                <ns4:anticipatedActual>Anticipated</ns4:anticipatedActual>
                                                        </ns4:reportingOfResults>

                                                        <ns4:registrationAndReportingCertification>N: No</ns4:
registrationAndReportingCertification>
                                                </ns4:postSubmissionInfo>

```
                              <ns4:ierParticipantData>
                                      <ns4:ierId>-1</ns4:ierId>
                                      <ns4:participantDataAttachment>
                                              <ns2:FileName>ParticipantLevelData-Template.csv</ns2:FileName>
                                              <ns2:MimeType>text/csv</ns2:MimeType>
                                              <ns2:FileLocation ns2:href="era://document/docservice
/dataservices/document/keyId/41507785/HSCTA"/>
                                              <ns3:HashValue ns3:hashAlgorithm="SHA-1"
>BAQOue13GPEeIyT+n6A4fEBV5FY=</ns3:HashValue>
                                      </ns4:participantDataAttachment>
                              </ns4:ierParticipantData>
                              <!-- <ns4:sourceUniqueValue>743162E814C2154A8D65AF403C96BA13</ns4:
sourceUniqueValue>-->
                      </ns4:HsctStudy>

                      <!-- Zero or more repetitions -->
          <hsc2:HsctDelayedOnsetStudy>
                      <hsc2:studyId>-1</hsc2:studyId>
            <hsc2:studyTitle>Delayed Study Title</hsc2:studyTitle>
            <hsc2:anticipatedClinicalTrial>Y: Yes</hsc2:anticipatedClinicalTrial>
            <hsc2:justification>
               <hsc2:attFile>
                  <att:FileName>att:FileName</att:FileName>
                  <att:MimeType>att:MimeType</att:MimeType>
                  <att:FileLocation att:href="era://document/docservice/dataservices/document/keyId/532135
/HSCTA" />
                  <glob:HashValue glob:hashAlgorithm="">MA==</glob:HashValue>
               </hsc2:attFile>
            </hsc2:justification>
          </hsc2:HsctDelayedOnsetStudy>
        </hsc:applicationsListWithStudies>
</hsc:SubmitExternalDataRequest>
```

8.2 Sample getExternalData REST xml request

```
<hsc:GetExternalDataRequest applId="9658888" xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService"/>
```

8.3 Sample submitPdfAttachmentForm REST multipart/form-data request parameter

```
externalPdfAttachment : {"applId":11125725}
attachment -- binary data
```

HSCT REST External SoapUI project sample:

Import project HSCT-S2S-REST-WS-soapui-project.xml.zip into SOAP UI. Update endpoint URL to the env in test.

8.4 Sample performHSSCheck REST xml request

```
<hsc:HSSCheckRequest xmlns:hsc="http://era.nih.gov/hsct/HsctExternalService">
     <hsc:applId>9997624</hsc:applId>
</hsc:HSSCheckRequest>
```