Output Without Institute Issues:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Lead/Investigator ID |  |  |  |  |
| Member ID |  |  |  |  |
| First Name | Jennifer | Michael | Thomas | Joseph |
| Last Name | Zacur | Goldfarb | Bander | Zahn |
| FOI Done | 1 | 1 | 1 | 1 |
| Date FOI done | 13-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Date Due Diligence Check Completed | 13-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Worldcheck Completed | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Inv. Worldcheck Completed | 1 | 1 | 1 | 1 |
| Date Inv. Worldcheck completed | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Inst. WorldCheck Completed | 1 | 1 | 1 | 1 |
| Date Inst. Worldcheck Completed | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Institute Compliance issue | No | No | No | No |
| Date 9002 DMC check |  |  |  |  |
| 9002 DMC Exclusion |  |  |  |  |

Output with Institute Compliance Issues:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Lead/Investigator ID |  |  |  |  |  |  |
| Member ID |  |  |  |  |  |  |
| First Name | Ismail | Olga | Eduard | Alena | Pavla | Filipovska |
| Last Name | Abdullah | Filipovska | Hrncir | Stumpfova | Apltauerova | Olga |
| FOI Done | 1 | 1 | 1 | 1 | 1 | 1 |
| Date FOI done | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Date Due Diligence Check Completed | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Worldcheck Completed | 26-10-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Inv. Worldcheck Completed | 1 | 1 | 1 | 1 | 1 | 1 |
| Date Inv. Worldcheck completed | 26-10-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Inst. WorldCheck Completed | 1 | 1 | 1 | 1 | 1 | 1 |
| Date Inst. Worldcheck Completed | 26-10-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 | 12-12-2017 |
| Institute Compliance issue | Yes | Yes | Yes | Yes | Yes | Yes |
| Date 9002 DMC check |  |  |  |  |  |  |
| 9002 DMC Exclusion |  |  |  |  |  |  |

var WorldCheckSite =

form.SiteSources.Where(x =>

x.SiteEnum == SiteEnum.WorldCheckPage).FirstOrDefault();

if (WorldCheckSite != null)

WorldCheckCompletedOn = WorldCheckSite.SiteSourceUpdatedOn;

var InstituteSite = form.SiteSources.Where(x =>

x.SiteEnum == SiteEnum.WorldCheckPage &&

x.SearchAppliesTo == SearchAppliesToEnum.Institute)

.FirstOrDefault();

if (InstituteSite != null)

InstituteWorldCheckCompletedOn =

InstituteSite.SiteSourceUpdatedOn;

var DMCCheck = form.SiteSources.Where(x =>

x.SiteEnum == SiteEnum.PfizerDMCChecksPage)

.FirstOrDefault();

if (DMCCheck != null)

DMCCheckCompletedOn = DMCCheck.SiteSourceUpdatedOn;

|  |  |  |  |
| --- | --- | --- | --- |
|  | Field in Output Report | Function ComplianceFormService. GenerateOutputFile |  |
|  | InvestigatorId | Investigator.InvestigatorId, |  |
|  | MemberId | Investigator.MemberId, |  |
|  | FirstName | Investigator.FirstName, |  |
|  | LastName | Investigator.LastName, |  |
|  | FOIDone | 1 |  |
|  | DateFOIDone | WorldCheckCompletedOn, | WorldCheckSite.SiteSourceUpdatedO |
|  | DueDiligenceCheckCompletedOn | Investigator.ReviewCompletedOn, |  |
|  | WordCheckCompletedOn | 1, |  |
|  | InvestigatorWorldCheckCompleted | Investigator.ReviewCompletedOn, |  |
|  | InvestigatorWorldCheckCompletedOn | WorldCheckCompletedOn, |  |
|  | InstituteWorldCheckCompleted | 1 |  |
|  | InstituteWorldCheckCompletedOn | InstituteWorldCheckCompletedOn, | InstituteSite.SiteSourceUpdatedOn |
|  | InstituteComplianceIssue | InstituteSite != null ? ToYesNoString(InstituteSite.IssuesIdentified) : "" |  |
|  | DMCCheckCompletedOn | DMCCheckCompletedOn | DMCCheck.SiteSourceUpdatedOn |
|  | DMCExclusion | DMCCheck != null ? ToYesNoString(DMCCheck.IssuesIdentified) : "" |  |
|  | Row | Row += 1 |  |

<soapenv:Envelope xmlns:soapenv="http://schemas.xmlsoap.org/soap/envelope/" xmlns:init="http://www.iconplc.com/InitiateDDASiSprintFindings/xsd/v3/initiateDDASiSprintFindingsMsg" xmlns:edh="http://edh.esb.iconplc.com">

<soapenv:Header/>

<soapenv:Body>

<init:DueDiligenceiSprintRequest>

<init:header>

<init:sender>sri</init:sender>

<init:timestamp>2017-08-20T11:06:25.000Z</init:timestamp>

<init:message\_id>sri1</init:message\_id>

</init:header>

<!--Optional:-->

<init:DDResults>

<edh:project>

**<!—Two Project Numbers ?-->**

<edh:projectNumber>9002</edh:projectNumber>

<!--Optional:-->

**<!—Two Sponsor Protocol Numbers ??-->**

<edh:sponsorProtocolNumber>202</edh:sponsorProtocolNumber>

</edh:project>

<edh:institutuions>

<!--Optional:-->

<edh:checksCompleted>

<!--1 or more repetitions:-->

<edh:check>

**<!—constant ??-->**

<edh:name>institution world check</edh:name>

**<!—Current Date ??-->**

<edh:date>2017-08-20</edh:date>

</edh:check>

</edh:checksCompleted>

**<!—constant ??-->** <edh:instituteComplianceIssue>true</edh:instituteComplianceIssue>

<!--Optional:-->

<edh:ddFindings>

<!--1 or more repetitions:-->

<edh:finding>

<edh:date>2017-08-20</edh:date>

<edh:type>Regulatory</edh:type>

<edh:regulatoryCode>OAI</edh:regulatoryCode>

<edh:regulatoryDeficiency>No</edh:regulatoryDeficiency>

<edh:worldCheckFinding>No</edh:worldCheckFinding>

<edh:comment>Test123</edh:comment>

</edh:finding>

</edh:ddFindings>

</edh:institutuions>

<edh:investigatorResults>

<!--1 or more repetitions:-->

<edh:investigatorResult>

<edh:investigatorId>101010</edh:investigatorId>

<!--Optional:-->

<edh:memberId>101010</edh:memberId>

<edh:firstName>Srinivas</edh:firstName>

<!--Optional:-->

<edh:middleName>A</edh:middleName>

<edh:lastName>Suri</edh:lastName>

**<!—constant ??-->**

<edh:ddStatus>Available</edh:ddStatus>

<!--Optional:-->

**<!—Current Date ??-->**

<edh:ddCompletedDate>2017-08-20</edh:ddCompletedDate>

<!--Optional:-->

<edh:checksCompleted>

<!--1 or more repetitions:-->

<edh:check>

**<!—Incorrect, the value is not related to World Check Site: If World Check Site exists then constant: ‘investigator world check’-->**

<edh:name>investigator world check</edh:name>

**<!—If World Check Site exists then WorldCheckPage.SiteSourceUpdatedOn -->**

<edh:date>2017-08-20</edh:date>

</edh:check>

</edh:checksCompleted>

<!--Optional:-->

**<!—If DMC Site Site exists then DMCExclusionPage .SiteSourceUpdatedOn -->**

<edh:dmc9002CheckDate>2017-08-20</edh:dmc9002CheckDate>

<!--Optional:-->

**<!—If DMC Site Site exists then ‘Exclusion’ -->**

<edh:dmc9002Exclusion>Exclusion</edh:dmc9002Exclusion>

<!--Optional:-->

<edh:ddFindings>

<!--1 or more repetitions:-->

<edh:finding>

**<!—?? DateOfInspection field is avaialble -->**

<edh:date>2017-08-20</edh:date>

**<!—?? Not Available in Findings -->**

<edh:type>Regulatory</edh:type>

**<!—?? Not Available in Findings -->**

<edh:regulatoryCode>OAI</edh:regulatoryCode>

**<!—?? Not Available in Findings -->** <edh:regulatoryDeficiency>No</edh:regulatoryDeficiency>

**<!—?? Not Available in Findings -->**

<edh:worldCheckFinding>No</edh:worldCheckFinding>

**<!—?? Observation Field is avaialable -->**

<edh:comment>TestingInv</edh:comment>

</edh:finding>

</edh:ddFindings>

</edh:investigatorResult>

</edh:investigatorResults>

</init:DDResults>

</init:DueDiligenceiSprintRequest>

</soapenv:Body>

</soapenv:Envelope>

For Discussion on 15Feb2018

Current DDAS validation in place:

1. Request payload accepts one or more investigator element(s)

2. Each investigator entry should have a role parameter

3. The accepted value for role parameter is either of PI or SubI

4. At least one of the investigator entry must have a role of PI

5. Only one investigator entry can have the PI role in a request payload

6. This means if you are supplying one investigator alone in the payload then it must have the PI role only

7. If more than one investigator is supplied in a payload, then one of them must have PI role. All others should have SubI role

8. If more than one investigator is supplied in a payload and more than one of them are having PI role, then it is invalid

But:

From iSprint the triggering point for Outbound message is on Campaign Member. So as per the workflow rule when we change PSSR Met field to “Yes” and with Date Responded it triggers the message to DDAS. We can change these values on any Investigator, it can be PI or SubI.

For each Campaign Member when we save in iSprint, we get only one Investigator Details. If this investigator is a PI then its saving in DDAS, But if this Investigator is NON PI (i.e. a SubI) then DDAS is not allowing to save.

1. Is it ok if DDAS throws error when we send a SubI role? Integration is not failing, but the investigator is not saving in DDAS due to the validation rule exception.
2. 2> How do we get an Investigator PI role whenever we save a SubI role Investigator? Should it be part of the Outbound Message from iSprint?
3. 3> Is the validation rule in DDAS already part of requirement? We were not aware this validation rule in DDAS until we tested with SubI. Can this be turned off in DDAS?

Please Note: From iSprint one Save is equal to One Outbound message, if we upload bulk CampaignMembers from APEX DATA LOADER then we will get multiple Investigators in one Outbound Message. But these bulk investigators may not be guaranteed to link to One Project Number/ Protocol Number and may not be all PI role Investigators as these are uploaded from excel data.

For any bulk load we debatch all Investigators and send requests to DDAS one after the other.

Issues identified by Clarity:

1. Is the Export to iSprint restricted to data received from iSprint?
   1. The application stores Investigator Data in the form of Compliance Form
      1. A Compliance Form comprises of
         1. Project Number – One or Two – format: Four numerals, a forward slash and Four numerals. dddd/dddd (1234/5678)
         2. Sponsor Protocol Number – Text One or Two
         3. Address
         4. Country
         5. Institute Name – One – optional
         6. Institute Findings:
            1. Sites to check – Zero or more. – These are pre-configured by the application admin.
         7. Address
         8. Country
   2. The application can export all Investigator data, stores

Institutuions/ checksCompleted/ check/name: -

Not found in RTM. Constant value: ‘institution world check’ generated by the application.

Institutuions/ checksCompleted/ check/date:

RTM line 19-D: Source Date where Source# = 14.

Q: Sites are configured by the DDAS Team and the site at position 14 may be moved to another position. In such an event the application logic will stop working.

Site Source Date: The Site Source Date is derived from the Finding – Date of Inspection. Site 14 can have more than one Finding, therefore more than one Date of Inspection.

Institutuions/ checksCompleted/instituteComplianceIssue - OK

RTM Line 20-D, To the Selected Institute Page with Values Yes & No

RTM Line 20-M, SiteSource/IssuesIdentified - if issues are identiied for source# 14, values is Yes else No

RTM Line 18 - Inst. Worldcheck Completed – A corresponding section is not found in xml.

Institutuions / ddFindings / ddFindings

Institutuions / ddFindings / ddFindings / date

<edh:date>2017-08-20</edh:date> - DateOfInspection avalailble.

<edh:type>Regulatory</edh:type>

<edh:regulatoryCode>OAI</edh:regulatoryCode> - Not Available

<edh:regulatoryDeficiency>No</edh:regulatoryDeficiency>- Not Available

<edh:worldCheckFinding>No</edh:worldCheckFinding>- Not Available

<edh:comment>Test123</edh:comment>- Observations available

Site Name is not mentioned in the output.

Define Site types like Workcheck Site / Regulatory Site etc.