03. Pre-requisites and Data Setup

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Contents

- Objective
- Standard PlaceHolders
 - Placeholder Expansion
- Data Setup Design
 - General guidelines for Data Setup steps
 - Data Setup configuration
- Data Setup
 - Trial
 - Trial Configuration
 - Configure a Trial for SOPs and Visit Types
 - Configure Trial level Visit Report Configuration for Visit Type
 - Configure Trial with additional Visit Report Templates
 - Configure Parallel Visit Type for Trial/Trial Country
 - Allow a Trial to be configured for Subject Monitoring
 - Configure a Trial with Vendor Legal Entity and Entity contact
 - Configuring a Trial for Subject Visit Design
 - Configure Investigator File Template
 - Configure a Trial Historic status
 - Source Data Items
 - Configure Trial level Visit Report Reviewer Defaults
 - Trial Last Country Setup
 - Trial Company Personnel
 - Adding Company Personnel to Trial Level
 - Company Personnel Blinding Type changes
 - Trial, Trial Country and Site Documents
 - Allow Trial, Country and Site level documents at Trial, Coun...
 - Set Trial, Country and Site documents to be Ready for use
 - <u>Updating Properties of the Documents</u>
 - Configure a Checklist for a Trial, Trial Country or Site Docu...
 - Creating Items for a Document Checklist
 - Adding a new Trial Document Version
 - Trial Country
 - Trial Country configured for last Site Confirmed
 - Configure EU CT 536/2014 Regulation
 - Trial Site
 - Trial Site Configuration
 - Configure a Trial Site for Subject Monitoring
 - Configure a Trial Site for Last subject setup
 - Configure a Trial site with Informed Consent
 - Setting the Status of a Trial Site
 - CCT at Trial Site Level
 - Trial Site Clinical Personnel

Trial Site Centres

Objective

- · Associating a site with a (primary) Centre
- Associating a Centre Location with a Trial Site

Please identify pre-requisite or data setup for in your team and update details in the below table. If the data setup is a one-time effort (e.g. Creating "Clinical Plan/Project"), then this muse be added to the pre-requisite scenarios.

Trial Site Contacts

• Create a new Trial Site Contact

Ensure you godater then this page (in the communication and avoid duplication). This will help to improve communication and avoid duplication.

SMV Check Lists

Standard Plage Holders Approvers

The following standardoplagelniologeneousless the following standardoplagelniologeneousless that the following standardoplagelniologeneousless standardoplagelniologeneousless

- Add Reviewer/Approver to a Standard Monitoring Visit
- Adding and Removing Company Personnel Visit Contacts ...
- Visits Reports
 - Create a new Formal Report Version for an Ongoing visit
 - To submit the report for review...
 - Perform an action on a visit Report Review
 - Finalise a Report
- New Clinical Personnel for an Ongoing Visit
- Investigator File Templates in Monitoring
- Issues
- Events
 - Enter Planned and Actual Trial Site Event
 - ERB/IES Submission for Trial Site
 - Enter Planned and Actual Trial Country Event Dates
 - Enter Planned and Actual Trial Event Dates
- Subject Visit Design
- Parallel Visits
 - Create a new Planned Parallel visit
 - Create a new Ongoing Parallel Visit
 - Configure Reviews/Approvers for Parallel Visits
 - Parallel Visit Reports
 - Setting a Parallel Visit Report to have a particular Status
- Subjects
 - Creating a Subject
 - <u>Updating Subject Properties</u>
 - Generation of Subject History
 - Transferring a Subject
- Subject Adverse Events
 - Creating a new Adverse Event
 - <u>Updating Adverse Event</u>
 - Deleting Adverse Event
- Subject Visits
 - Completing a Subject Visit

	j <u>ecting Subject Visits</u> Description <u>Monitoring Visit Item</u>	Examples
• Rec • Centres • Cre • Ass • Clinical I • Compan • Cre • Upc • Adc • Cre • Field Hic • Countrie	ating a Centre orlain will be converted into the unique number based on an epoch time ersonnel. The first value used will be an Epoch time with y the first value used will be an Epoch time with y the first three digits replaced by a Random ating about the personnel in Reference to a Company Personnel in a thread safe manner to a Company Personnel in Note: This will be used across all Scenarios ating a Browser Set for a Personnel in the Reference of the personnel in thread a Browser Set for a Personnel in the Reference of the personnel in the Reference of the	Epoch Time 1594278574492 159 replaced by random number e.g. 654 Scenario 1 Auto{time}> Auto6544278574492 Scenario 2 Potter{time}> Potter6544278574493 Auto6544278574494 Scenario 1 Albert{time}> Albert6544278574495
• General • Ale current date[+/-n]	Windows handling ts This will be converted into the Current Date, offset by n of days (if supplied)	{current date}> 09-Jul-2020 {current date+4}> 13-Jul- 2020 {current date-5}> 04-Jul-2020
current year [+/-n]	This will be converted into the current Year, offset by n of years (if supplied)	{current year}> 2021 {current year+4}> 2025 {current year-5}> 2016
current time(in sec)	This will be converted in the the current time (to the nearest minute), into the number of seconds since midnight	Current time 09:38:30 {current time (in sec)}> 34680 Current time 09:38:31 {current time (in sec)}> 34740
counter[+n]	This will be converted into an number, which starts as 1 and is incremented after each use Note: a new counter is produced for each Scenario.	Scenario 1 {counter}> 1 {counter}> 2 {counter+40}> 43 Scenario 2 {counter+1000}> 1001 {counter+500}> 502 {counter}> 3
unique Country Code	This will generate String of three random AlphaNumeric characters for use as a Country Code which does not currently exist in the database. Note: There is a very small possibility of a clash if two or more usages of the placeholder generate identical Strings before one of them is saved to the database.	

7		
PlaceHolder	Description	Examples
unique Security Role Code	This will generate a String of three random AlphaNumeric characters for use as a Security Role Code which does not currently exist in the database. Note: There is a very small possibility of a clash if two or more usages of the placeholder generate identical Strings before one of them is saved to the database.	
unique Visit Type Code	This will generate a String of six random AlphaNumeric characters for use as a Visit Type Code which does not currently exist in the database. Note: There is a very small possibility of a clash if two or more usages of the placeholder generate identical Strings before one of them is saved to the database.	
<n> character string</n>	This will be converted to a constant String of <n> characters. n cannot be more than 4000 characters Note: Multiple uses will always generate the same text.</n>	{4000 character string} - generates a string of 4000 characters {60 character string} generates a string of 60 characters

Placeholder Expansion

Placeholder expansion has been updated to support embedded placeholders. So for example the following situation will expand out the embedded placeholder items.

• json item pointing to another item (e.g. extract from CommonPredefinedData.json)...

```
// Items for data setup
"Item 1 Code" : "A1" ,
"Item 1 Description" : "AUTOMATION MONITORING ITEM 1" ,
//items for test scenarios
"Monitoring Item 1 Code" : "A1.A1.A1.A1" ,
```

Implemented support for the following...

```
"Monitoring Item 1 Code" : "{Item 1 Code}.{Item 1 Code}.{Item 1 Code}. \
```

Data Setup Design

There are steps which have been created in order to setup the required data for an automation scenario. If an existing step cannot be found then it will have to be created.

Note: In some instances a step may exist for either WebApp or Services automation, but not the other. If it is required for both then it should be created using the same format as the module in which it already exists.

General guidelines for Data Setup steps

When setting up data there will generally be a basic step which performed the required option. This will use default data with certain properties of the element being stored in Scenario Data. There are then variations of that step which allow multiple instances to be identified and/or customised.

e.g.

In order to see which Element Items can be specified, look in the DtoMapping class for the Element(s).

Data Setup configuration

The Data Setup steps specified in the Scenarios are mapped to entries in the file GenerateDataActionMappings.json.

This file contains details of each action which can be performed, and the configuration files which need to be used to perform the action, and whether any other actions need to be performed first.

e.g. Given a new Trial Site with Primary Investigator` exists
will have an entry in the GenerateDataActionMappings.json file of

```
"new Trial Site with Primary Investigator": {
    "requiredSetup": [
        "new Primary Investigator"
    ],
    "defaultFile": "testData/site/DefaultTrialSite.json",
    "finalFile": "testData/site/NewTrialSiteWithPrimaryInvestigator.json"
},
```

So before the Trial site can be created, a new Primary Investigator needs to be created. The details which will be used for Trial Site are then specified in the defaultfile and finalfile These two files contain details of the Dtos which need to be generated in order to call the relevant Business Tier method.

The entries in the default and final file are combined, this allows common values to be specified in the default file, and then specific values for the action to be specified in the final file.

The files contain arrays of Dtos which are combined usnig the following logic

- When combining the Default and New files, if there is an element at the same index in both files then it will be used.
- If there is an element at index 'n' in the New file, but no corresponding element at index 'n' in the 'Default File' then the first element in the 'Default file' will be used.
- If there is an element at index 'n' in the Default file, but no corresponding element at index 'n' in the 'New File' then only the default entry will be used.

• Note: If DataTable properties are used in the feature file then they will be applied to ALL array elements.

Data Setup

Trial

• Create a Trail
`Given a "new Trial" exists

Trial Configuration

Configure a Trial for SOPs and Visit Types

API Automation

```
Given the "new trial" is configured with "SOPs and Visit Report Config"
 Property
                                       Value
                                       {SOP Number For CheckList}
 SOP Number for Checklist
 Visit Type for Checklist
                                       | {Visit Type For CheckList}
 Visit Report Adverse Event Section
 Visit Report Checklist Section
 Visit Report Pages Collected Section | N
 Visit Report Data Monitoring Section | N
 Visit Report Narrative Section
                                       N
 Visit Report Issue Section
                                       l N
 Visit Report Informed Consent Section | N
| Visit Report Distribution Transfer | N
```

Web App Automation

Configure Trial level Visit Report Configuration for Visit Type

Configure Trial with additional Visit Report Templates

This allows additional Visit Report Templates to be added to a Trial

```
And the "Trial" is configured for "SOPs and Visit Report Config"
And the "Trial" is configured with additional "Visit Report Templates"
  Template
                Property
                 | Visit Type Code
   Template 1
                                                            {Visit Type Code}
   Template 1 | Visit Report Template Number
                                                             {Visit Report Template Number 1}
   Template 1
                 Visit Report Template Name
                                                             {Visit Report Template Name 1}
   Template 1
                 | Visit Report Template Mandatory Flag
   Template 1 | Visit Report Template Distribution Flag
Template 2 | Visit Type Code
                                                             {Visit Type Code}
   Template 2
                 | Visit Report Template Number
                                                             {Visit Report Template Number 2}
   Template 2 | Visit Report Template Name
                                                             {Visit Report Template Name 2}
   Template 2
                 | Visit Report Template Mandatory Flag
  Template 2
                 | Visit Report Template Distribution Flag | N
```

Configure Parallel Visit Type for Trial/Trial Country

This will perform the necessary calls to Configure a Trial and/or Trial Country to use the {Parallel Visit Type}

```
Given the "Trial" is configured for "Parallel Visit"

And the "Trial Country" is configured for "Parallel Visit"

Or

Given the "Trial and Trial Country" is configured for "Parallel Visit"
```

To specify the Parallel Visit Type Code then use

Allow a Trial to be configured for Subject Monitoring

```
Given the "trial" is configured for "Subject Monitoring"
```

Configure a Trial with Vendor Legal Entity and Entity contact

```
Given the "Trial" is configured for "Vendor Legal Entity and Contact"
```

This relies on the the following predefined data being configured

- Vendor Legal Entity Code
- Vendor Legal Entity Contact Code or use

Configuring a Trial for Subject Visit Design

See Subject Visit Design

Configure Investigator File Template

Allows to check investigator file template checkbox at trial parameters page

```
And the "Trial" is configured for "Investigator File Template"
```

 Confirm Investigator Trial Template at Trial/Country level Allows to include investigator file templates to trial

```
And the Investigator File Template is confirmed for "Trial"

And the Investigator File Template is confirmed for "Trial", configured as | Property | Value | |
| Document Item Category No | {Document Item 2 Category No} | |
| Document Item Type No | {Document Item 2 Type No} | |
| Confirmed By | {User Personnel No} | |
| Confirmed Date | {current date-10} |
```

Note: "Trial" can be replaced with "Trial Country" in order to confirm its use at Country level e.g.

```
And the Investigator File Template is confirmed for "Trial Country"
```

Configure a Trial Historic status

This will configure a Trials Historic Status so can be marked as Archived.

The following will set the status of the last added Trial in scenario context.

To set the status of a specific Trial if added more than one....

Source Data Items

Configure Source Data Items for a Trial

Associate Source Data Items for particular Visits

```
Given Trial Source Data Item "{Source Data Item 1}" is configured for Visits
 Visit
         Assigned
 SCREEN1
           Yes
 SCREEN2 No
 BASE1
         No
TREAT1 Yes
And Trial Source Data Item "{Source Data Item 2}" is configured for Visits
 Visit
 SCREEN1 | No
 SCREEN2
          Yes
 BASE1
          Yes
 TREAT1 No
```

Configure Trial level Visit Report Reviewer Defaults

This will configure the visit report reviewer defaults at trial level.

```
And the "Trial " is configured for "Visit Report Reviewer Defaults "

And the "Trial " is configured for "Visit Report Reviewer Defaults "with | Property | Value | | Allow Finalisation | Y | | E-sign Review | Y | | E-sign Approval | N |
```

Trial Last Country Setup

Allow a Trial to be configured with Last Country Set Up flag set

```
And the " Trial " is configured for " Last Country Set Up "
```

Trial Company Personnel

Adding Company Personnel to Trial Level

```
And a "new Trial Company Personnel" exists, identified as "TPER1", configured as
| Property | Value |
| Company Personnel No | {PER1User Personnel No} |
```

Company Personnel Blinding Type changes

Company personnel blinding type change at trial level (Blinded to unblinded and vice versa).

```
And a "new Trial Site With Primary Investigator" exists
And a "new Trial Company Personnel" exists
And update "Trial Company Personnel" is configured for "Blinding Type" with

| Property | Value |

| Company Personnel No | {User Personnel No} |

| Company Personnel Blinding Type | {Unblinded} |

| Company Personnel Blinding Type Change Reason | API Automation visit types testing |
```

Note: For Unblinded to Blinded use Company Personnel Blinding Type as {Blinded}

Trial, Trial Country and Site Documents

Allow Trial, Country and Site level documents at Trial, Country or Site level to be configured

This will add document items at Trial, Country or Site level. Each level requires the previous level to be configured.

The following will add all the document level items and item 4 will have the document flag set.

```
And a " new Level 1 Trial Document " exists for the "Trial"
And a " new Level 2 Trial Document " exists for the "Trial"
And a " new Level 3 Trial Document " exists for the "Trial"
And a " new Level 4 Trial Document " exists for the "Trial"
```

The default code/description can be overridden....

```
And a " new Level 1 Trial Document " exists for the "Trial"

And a " new Level 2 Trial Document " exists for the "Trial", configured as | Property | Value | |
| Document Code | GH | |
| Document Description | Test Level2 |
```

The document flag can be set for the level required (except level 1) and optional identifiers can be used.

```
And a " new Level 1 Trial Document " exists for the "Trial"

And a " new Level 2 Trial Document " exists for the "Trial", identified as " Doc Level 2 "

And a " new Level 3 Trial Document " exists for the "Trial", identified as " Doc Level 3 ", configured as | Property | Value |

| Document Flag | Y |
```

In order to create documents for Trial Country and Trial Site just replace Trial Document with Trial Country Document Or Trial Site Document, i.e.

```
And a "new Level 1 Trial Country Document" exists for the "Trial"
And a "new Level 1 Trial Site Document" exists for the "Trial"
```

In order to create documents at the Trial Country Level just replace the for a "Trial" with for a "Trial Country" Or for a "Trial Site", i.e.

```
Given a "new Level 1 Trial Country Document" exists for the "Trial Country"

And a "new Level 2 Trial Country Document" exists for the "Trial Country"

And a "new Level 3 Trial Country Document" exists for the "Trial Country"

And a "new Level 4 Trial Country Document" exists for the "Trial Country"

Given a "new Level 1 Trial Site Document" exists for the "Trial Site"

And a "new Level 2 Trial Site Document" exists for the "Trial Site "

And a "new Level 3 Trial Site Document" exists for the "Trial Site "

And a "new Level 4 Trial Site Document" exists for the "Trial Site "
```

Shorted Version

In some case it is possible to configure multiple level document using a single Step. e.g.

```
And a "new Trial Country Documents upto Level 4" exists for the "Trial"
And a "new Trial Country Documents upto Level 4" exists for the "Trial Country"
```

These steps are configured in the GenerateDataActionMapping.json file to call the relevant steps. e.g.

Set Trial, Country and Site documents to be Ready for use

This will set either, all or the specified Trial, Trial Country or Trial site documents as Ready For Use for a Trial/Trial Country

To set all documents the following step should be used...

```
And all "<document level>" Documents for the "<Application level>" are set as Ready for Use
```

Where <document level> is the level at which the Documents are applicable, i.e. Trial, Trial Country, or Trial Site

and <Application Level> is the application level at which the documents are being marked ready for use, i.e. Trial, Trial Country or Trial Site

e.g.

```
And all "Trial" Documents for the "Trial" are set as Ready for Use
And all "Trial Country" Documents for the "Trial" are set as Ready for Use
And all "Trial Country" Documents for the "Trial Country" are set as Ready for Use
```

To set a specified selection of documents ...

```
And the following "Trial" Documents for the "Trial" are set as Ready for Use | Document Code | Document Description | | {Trial Document Level 4 Code} | {Trial Document Level 4 Description} |
```

Or if more than 1 required (and a placeholder used for a document)...

Updating Properties of the Documents

The Properties of the document at Level 2, 3 or 4 can be updated at the Trial, Trial Country or Site Levels

or

Configure a Checklist for a Trial, Trial Country or Site Documents

Once a Document has been created using

then a Checklist can be created for the Document using

```
And a "new Level 4 Trial Document Checklist" exists for the "Trial"

Or

And a "new Level 4 Trial Document Checklist" exists for the "Trial", configured as | Property | Value |
```

Checklists can be created at different levels by changing the "Trial" e.g.

```
And a "new Level 4 Trial Country Document Checklist" exists for the "Trial Country"
```

Desc

Creating Items for a Document Checklist

Document Checklist Description

Create or Update Checklist Items for Document, this requires that a document Checklist has been created.

```
And a "new Level 4 Trial Document Checklist" exists for the "Trial"

And "Trial" Document Checklist Items for the "Trial" are configured as

| Document Checklist Item No | Document Checklist Item Display Sequence No | Document Checklist Item Descri
| 1 | 2 | Checklist Item Seq 2 |
| 2 | 1 | Checklist Item Seq 1 |
```

Note: The "Document Checklist Item No" and "Document Checklist Item Display Sequence No" are not mandatory. If not specified then they will be defaulted to the row in the table, i.e. 1, 2, etc,

Adding a new Trial Document Version

Trial Country

Trial Country configured for last Site Confirmed

Allow a Trial Country to be configured with Last Trial Site Confirmed flag set.

```
And the "Trial Country" is configured for "Last Trial Site Confirmed"
```

Configure EU CT 536/2014 Regulation

This will configure the Configure EU CT 536/2014 Regulation for a Trial Country

```
And the "Trial Country EU CT 536/2014 Regulation " is updated with
Property
 Event Status
                          {EU 536/2014 Regulation Event Status Started}
 Event Reason
                         Some reason
                         | Some comments
 Event Comment
 Start of Trial Date
                         | {current date+1}
 End of Trial Date
                         {current date+2}
 Temporary Halt Date
                         {current date+3}
 Restart of Trial Date | {current date+4}
 Recruitment Start Date { current date+5}
 Recruitment Restart Date | {current date+6}
| Recruitment End Date
                      {current date+7}
```

Trial Site

Creating a Trial Sit

٩

without a Primary Investigator

```
Given a "new Trial Site without Primary Investigator" exists
```

with a Primary Investigator

```
Given a "new Trial Site with Primary Investigator" exists
Given a "new Trial Site with Primary Investigator" exists, identified as "CLP1"
```

Trial Site Configuration

Configure a Trial Site for Subject Monitoring

```
" gherkin
Given the "Trial Site" is configured for "Subject Monitoring"
"
```

Configure a Trial Site for Last subject setup

```
And the " Trial Site " is configured for " Last Subject Set Up "
```

Configure a Trial site with Informed Consent

or

Setting the Status of a Trial Site

Update trial site status to Delay, Cancel or Stop

CCT at Trial Site Level

• Create a Trial Site Fund

Authorise a fund at Trial Site Level
 And the Fund is authorised
 Or

• Add Financial Agreement to the Fund

Add Financial Agreement fee items
 Allows just fee items to be added to the financial agreement

```
And the Fund Agreement has Fee Items added | Property | Value | Fund No | {Fund No} |
```

Add Financial Agreement Fees with new effective date

Note: this doesn't currently allow setting of a date and uses default date: 01-Jan-1900

Configure fund payment rule for a Trial Site

Generate a fund Payment Request number at Trial Site level

```
And the "Trial Site" is configured for "Fund Payment Request"
```

Trial Site Clinical Personnel

 Creating a new Clinical Personnel and associates them with the Trial Site Given a "new Trial Site Clinical Personnel" exists
 Given a "new Trial Site Clinical Personnel" exists, identified as "CLP2"

```
Given a "new Trial Site Clinical Personnel" exists, identified as "CLP2", configured as
                               Value
 Potential Investigator Flag
 Title
                               Miss
 First Name
                               Amelia
 Middle Name
                              Fiona
 Surname
                               Stark_{time}
  Suffix
                               MSc
                              | amelia.Stark@clinic_rain.com
 Email Address
                              555-777-999
 Phone Number
```

• Updating a Trial Site Clinical Personnel

```
And the Trial Site Clinical Personnel is updated | Property | Value | Role Code | CLP | Start Date | {current date-20} | End Date | {current date+100} |
```

• Assigning a new Role to the Trial Site Clinical Personnel

```
And the Trial Site Clinical Personnel has another role | Property | Value | Role Code | LAB | Start Date | {current date-20} | End Date |
```

Associate a Clinical Personnel to a Site with an Ongoing visit (API Only)

Trial Site Centres

Associating a site with a (primary) Centre

```
And the Trial Site is associated with Centre "{CEN1 Centre No}"
```

Associating a Centre Location with a Trial Site

Trial Site Company Personnel

Creating a new Company Personnel for a Trial Site (API only)

```
Given a "new Trial Site Company Personnel " exists
```

```
And a "new Trial Site Company Personnel" exists, identified as "PER1", configured as 
| Property | Value | 
| Personnel No | {User Personnel No} |
```

Associating an existing User as a Company Personnel for a Site (API Only)

```
Given a "new Trial Site Company Personnel" exists with the role "OCC", identified as "PER1", configured as
  Property
                      | Value
   Occupation Code
                      000
   Security Role Code | OCC
   Role Start Date | {current date}
  Role End Date
                      {current date+50}
And a "new Trial Site Company Personnel" exists with the role "CRA", identified as "PER2", configured as
                      Value
   Property
   Occupation Code
                      OCC
   Security Role Code | OCC
   Role Start Date | {current date-10}
   Role End Date
                      {current date+100}
```

Trial Site Contacts

Create a new Trial Site Contact

```
And a "new Trial Site Clinical Personnel" exists, identified as "TSPer1"
And a "new Trial Site Contact" exists, identified as "Site Contact1", configured as
| Property | Value |
| Contact Clinical Personnel 1 | {TSPer1 Clinical Personnel No} |
```

The following Scenario Data will be created

- <Prefix> Contact No
- <Prefix> Contact Method
- <Prefix> Contact Method Description
- <Prefix> Contact Type
- <Prefix> Contact Type Description
- <Prefix> Contact Status
- < Prefix > Contact Status Description
- <Prefix> Contact Date
- <Prefix> Contact Time
- <Prefix> Contact Direction
- <Prefix> Contact Subject
- <Prefix> Contact Completed
- <Prefix> Contact Clinical Personnel [1-5]
- <Prefix> Contact Company Personnel [1-5]

Standard Monitoring Visits

Creating/Starting/Completing

• Creating a Trial Site with planned visit in single step (currently only in API automation)
Given a "new Trial Site with Planned Visit" exists

Creating a new visit for an existing Trial Site

```
Given a "new planned visit " exists
```

• Updating a visit

Starting a visit

```
Given the visit is started
Given the visit "VISIT1" is started
```

Starting a Visit by a particular monitor of the visit

```
Given the visit "VISIT2" is started by "{ACTPER2 User Personnel No}"
```

Completing a Visit

```
And the visit is completed
And the visit "VISIT1" is completed
```

Aborting/Resetting a Visit

```
And the visit is reset
And the visit "VISIT1" is reset
```

SMV Check Lists

Updating SMV Checklist Information

```
Given the checklist "{CheckList 1 Number}" question "{Checklist 1 Question 1 Title}" is updated on "HOST_MC | Property | Value | Result Flag | Y | Comment | checklist question comment updated |
```

SMV Reviewers/Approvers

Configuring the default Visit Report Reviewer Details

See Configure Trial level Visit Report Reviewer Defaults

Add Reviewer/Approver to a Standard Monitoring Visit

Adds the Personnel with the specified Personnel No to a Review/Approver for a Visit, defaulting to most recently created visit.

Adding and Removing Company Personnel Visit Contacts during Ongoing Visit

```
And visit "VISIT1" is updated on schema "HOST_MONITORING"
| Property | Value |
| Visit Contact Company Personnel 1 | {ACTPER1 User Personnel No} |
| Visit Contact Company Personnel 2 | {ACTPER2 User Personnel No} |
| Visit Contact Clinical Personnel 1 | {CLP2 Clinical Personnel No} |
```

Visits Reports

Create a new Formal Report Version for an Ongoing visit

```
Given a "new Formal Report Version for Ongoing Visit" exists
```

or for a specific Template

To submit the report for review...

```
Given a "new Report submission for Ongoing Visit" exists
```

or for a specific Template

Perform an action on a visit Report Review

The allowed actions are allowed

- Completed
- Approved
- Rejected

Finalise a Report

This will finalise the report associated with the last visit added to scenario context....

```
And the Report is finalised
```

New Clinical Personnel for an Ongoing Visit

Add 'New Clinical Personnel For Visit' on Monitoring for an ongoing visit.

```
And a "new Clinical Personnel for visit" exists, for an ongoing visit "VISIT1", identified as "NEWCLP1", cc | Property | Value | | Clinical Personnel Investigator Flag | Y | | Clinical Personnel Title | Mr | | Clinical Personnel Forename | Vinay | | Clinical Personnel Middle Name | Sharma | | Clinical Personnel Surname | HolmesLast_New_{time} | | Clinical Personnel Suffix | Ms | | Clinical Personnel Email | vinay.sharma@clinic.com | | Clinical Personnel Phone | 7799111 | | Role Code | CLP | | Role Description | Clinical Personnel Role | | Country Code | {Trial Country Code} |
```

Note: this dto doesn't seem to be setting the role when viewing in MySites.

Investigator File Templates in Monitoring

Update Investigator File Template in Monitoring for an ongoing visit

Configure investigator file template checkbox at trial level
 See Configure Investigator File Template

Issues

Create an Issue at Trial Level

```
Given a "new Trial Issue" exists
Given a "new Trial Issue" exists, identified as "ISSUE2"
```

```
Given a "new Trial Issue" exists, identified as "ISSUE2", configured as
                       Value
 Property
 Issue Description
                        API Automation Open Issue Description
 Is-protocol-deviation | N
 Comments
                       API Automation Open Issue Comments
 Issue Action
                       API Automation Open Issue Action
                       API Automation
 Issue Source
                       N
 Issue Closed Flag
 Issue Resolved Flag
                       N
```

Create at Issue at Trial Country Level

```
Given a "new Trial Country Issue" exists
Given a "new Trial Country Issue" exists, identified as "ISSUE2"
```

```
Given a "new Trial Country Issue" exists, identified as "ISSUE2", configured as
 Property
                         Value
 Issue Description
                         API Automation Open Issue Description
 Is-protocol-deviation | Y
 Comments
                       API Automation Open Issue Comments
 Issue Action
                       API Automation Open Issue Action
 Issue Source
                       | API Automation
 Issue Closed Flag
                       N
 Issue Resolved Flag
                       N
```

Create an Open Issue at Trial Site Level

Create a Closed Issue at Trial Site Level

Update an Issue at Trial Site Level
 Note: the issue must have been created with an Identifier

Creating a new Checklist Issue

```
Given a "new Trial Site Open Issue" exists on "HOST_MONITORING" schema, identified as "ISSUE1", configured
 Property
                            | Value
  Issue Description
                              Automation Issue Description with Checklist 1, 1, 2
 Is-protocol-deviation
                             Automation Issue Comments
 Comments
 Issue Action
                             Automation Issue Action
 Issue Source
                             Automation
 Checklist Version
                             {Checklist 1 Version}
                              {CheckList 1 Number}
 Checklist Number
 Checklist Question Number | {Checklist 1 Question 1 Number}
```

Events

Enter Planned and Actual Trial Site Event

or an alternative of

```
And the following "Trial Site Events", identified as, "<identifier>", are updated
```

It is also possible to update the Trial Site Event comments

Note:

Any Event Description can be used, not just the ones shown above
Actual Date cannot be set for IRB/IEC Submission or IRB/IEC Approval
Either the Planned Date or Actual Date columns can be omitted if you only want to update one of the dates.

Scenario data will be created as follows

```
<Identifier> <Event Description> Event No
<Identifier> <Event Description> Planned Date
<Identifier> <Event Description> Actual Date
```

ERB/IES Submission for Trial Site

```
And a "new Trial Unit IRB/IEC Submission" exists, configured as
| Property | Value |
| IRB/IEC Submission Date | {current date-20} |
| IRB/IEC Approval Date | {current date-19} |
```

If you only want the Submission Date then remove the line with the Approval Date, and vice versa By default this will rollup the Dates to the the Tu Events. If that is not required then also need to specify a property/value of

```
Roll Up Ethical Events | N |
```

Enter Planned and Actual Trial Country Event Dates

```
And the following "Trial Country Events" are updated

| Event Description | Planned Date | Actual Date |

| Finance Agreement | {current date-28} | {current date-23} |

| Country Protocol Approval | {current date-25} | {current date-25} |

| Regulatory Submission | {current date-28} | {current date-22} |

| Regulatory Approval | {current date-27} | |
```

or an alternative of

```
And the following "Trial Country Events", identified as, "<identifier>", are updated
```

Note:

If there are any data which cannot be updated due to current configuration of the Trial then the update will fail.

Either the Planned Date or Actual Date column can be omitted if you only want to update one of the dates.

Scenario data will be created as follows

```
<Identifier> <Event Description> Event No
<Identifier> <Event Description> Planned Date
<Identifier> <Event Description> Actual Date
```

Enter Planned and Actual Trial Event Dates

```
And the following "Trial Events" are updated

| Event Description | Planned Date | Actual Date |
| Synopsis Started | \{current date-28\} | \{current date-23\} |
| CRF/Data Design Started | \{current date-27\} | \{current date-22\} |
| CRF Approved | \{current date-26} | \{current date-21\} |
| CRF Production Complete | \{current date-25\} | \{current date-20\} |
| 1st Regulatory Submission | \{current date-24\} | |
| 1st Regulatory Approval | \{current date-23\} | |
| 1st IRB/IEC Submission | \{current date-22\} | |
| Trial Start Up Meeting | \{current date-21\} | \{current date-16\} |
```

or an alternative of

```
And the following "Trial Events", identified as "TR", are updated
```

Note:

If there are any data which cannot be updated due to current configuration of the Trial then the update will fail

Either the Planned Date or Actual Date column can be omitted if you only want to update one of the dates.

Scenario data will be created as follows

```
<Identifier> <Event Description> Event No
<Identifier> <Event Description> Planned Date
<Identifier> <Event Description> Actual Date
```

Subject Visit Design

• This will create/configure a Trial to have a Subject Visit Design. The actual design is specified in associated Json files, [Default/New]SubjectVisitDesign.json

Web App Automation

```
Given a "new trial with Subject visit design" exists

API Automation

Given the "Trial" is configured for "Subject Visit Design"
```

Creating a Visit Arm

Assuming a subject Visit Design has already been created, this will create a Visit Arm

```
Given the "Trial" is configured for "Subject Visit Arms", identified as "Arm1", with
| Property | Value |
| Visit Arm Description | Visit Arm 1 |
| Visit Arm No | 1 |
```

Parallel Visits

Create a new Planned Parallel visit

```
Given a "new planned Parallel Visit" exists
```

Create a new Ongoing Parallel Visit

This will create an Ongoing Remote Visit with a past start date Given a "new ongoing Remote Visit" exists

Configure Reviews/Approvers for Parallel Visits

```
And the "Remote Visit Reports" is configured for "Reviewer/Approver" with
| Property | Value |
| Remote Visit Reviewer Number | {Reviewer Company Personnel No} |
| Remote Visit Approver Number | {Approver Company Personnel No} |
```

Parallel Visit Reports

Generate formal version of a Parallel Visit Report

```
And a "new Formal Report for Ongoing Remote Monitoring Visit" exists
```

Submit a Remote Monitoring Report for Review

```
And a "new Report Review submission for Ongoing Remote Monitoring Visit" exists
```

Setting a Parallel Visit Report to have a particular Status

```
And the Remote Visit Report Review is "Rejected" by "Reviewer", with | Property | Value | Remote Visit Report Review Comment | Review Completed |
```

The allowed actions are

- Completed
- Rejected

Subjects

Creating a Subject

```
And a "new Subject" exists ` And a "new Subject" exists, identified as "Subj2"``
And a "new Subject" exists, identified as "Subj2", configured as
 And a "new Subject" exists on "HOST_MONITORING" schema, identified as "Sub2", configured as
   Property
   Unique No
                            {counter+40}
   Randomisation No
                            {counter+60}
   Initials
   Gender
   Date of Birth
                            {current date-10000}
   Informed Consent Date
                            | {current data-20}
   Informed Consent Version | 1.10
 Visit Arm No
```

Note: the Unique No and Randomisation Number making use of a placeholder {counter+n} in order to ensure that if multiple Subjects are created in the same Scenario then the Numbers assigned to them will be unique.

Updating Subject Properties

Allows updating of Subject Properties

```
When the "Subject", "Sub1", is updated with
 Property
                                   {counter+40}
 Randomisation No
 Initials
                                   QAZ
 Gender
                                   М
 Date of Birth
                                   02-Apr-1945
 Confirmed Flag
 Subject Informed Consent Date | {current date-20}
 Subject Informed Consent Version | {V1.20 Trial Site Informed Consent Version}
                                  | {Arm2 Visit Arm No}
 Visit Arm No
 Treatment Withdrawal Reason
                                 | {Withdrawal Reason - Adverse Event}
 Treatment Withdrawal Date
                                 | {current date-1}
 Treatment Withdrawal Description | Got bored went home
 Trial Withdrawal Reason | {Withdrawal Reason - Adverse Event}
 Trial Withdrawal Date
                                   {current date-1}
 Trial Withdrawal Description | Got bored went home
```

or for a specific Schema use

```
Given the "Subject", "Sub1", is updated on the "HOST_MONITORING" schema with
```

Generation of Subject History

Allows a subject history to be generated. **Note** This ONLY works on the monitoring Schema, so this must be specified in the step. e.g.

```
And a "new Subject History" exists on "HOST_MONITORING" schema
```

This can also be expanded to specify an Identifier and specific values, including if required a specific subject e.g.

```
And a "new Subject History" exists on "HOST_MONITORING" schema, identified as "SubHist2", configured as 
| Property | Value | 
| Entry No | {Sub1 Entry No} | 
| Subject History Date | {current date-5} | 
| Subject History Comment | Subject History Comment {time} |
```

The following Scenario Data will be created

- prefix> Subject History No The internal No of the History element which has been created.
- prefix> Subject History Date The Date of the Subject history entry
- prefix> Subject History Comment the Comment of the Subject history entry

Transferring a Subject

Two Sites must be set up with Identifiers and one or more Subject(s) created for one of the sites.

The following step can be used to transfer the last Subject created

```
And the Subject is transferred from "Site1" to "Site2"
```

or this step can be used to transfer a particular Subject, where "Sub1" is the identifier specified when the Subject was created.

```
And "Sub1" is transferred from "Site1" to "Site2"
```

Subject Adverse Events

Creating a new Adverse Event

Assuming a subject has already been created, this will create an adverse event.

Note: The Event Type Code property must be provided.

```
And a "new Adverse Event" exists, configured as

| Property | Value |
| Event Desc | My first Adverse Event desc |
| Subject Withdrawn Due To Event Flag | Y |
| Onset Date | {current date} |
| Resolved Date | {current date} |
| Outcome Code | RS |
| Event Type Code | {Adverse Event Type Code - Non-Serious} |
| Event Severity Code | {Adverse Event Severity Code - Mild} |
| Event Relation Code | {Adverse Event Relation Code - Non-Related} |
| Company Notified Date | {current date} |
| IRB/IEC Notified Date | {current date} |
| Date First Checked | {current date} |
| Date Last Checked | {current date} |
| Comments | My first Adverse Event comment |
```

It is possible to create an Adverse Event on the Monitoring Schema using

```
And a "new Adverse Event" exists on "HOST_MONITORING" schema, configured as ...
```

Updating Adverse Event

Assuming a subject adverse event has already been created, this will update the adverse event. The Event Type Code property must be provided.

Note: on the "HOST_MONITORING" schema can be omitted to update the adverse event on the Host Schema

Deleting Adverse Event

Assuming a subject adverse event has already been created

```
And the "Adverse Event", "ADV1", is deleted with 
| Property | Value | 
| Entry No | {Sub3 Entry No} |
```

```
And the "Adverse Event", "ADV1", is deleted on the "HOST_MONITORING" schema with | Property | Value | | Entry No | {Sub3 Entry No} |
```

Subject Visits

Completing a Subject Visit

This will complete the default visit in the 'DefaultConfigSubjectWithSubjectVisit.json' file using the current date.

And the "Subject" is configured for "completing a Subject Visit"

Completing a Subject visit using the date specified

• Complete the visit specified with a blank date

• If completing a subject visit for a particular Visit Arm then the visit Arm no must be specified i.e.

Projecting Subject Visits

```
And the Subject, "Sub1", has their Visits Projected based on Visit "BASE1"

And the Subject, "Sub2", has their Visits Projected based on "Last Completed Visit"

And the Subject, "Sub3", has their Visits Projected based on "First Visit"
```

Note: the following can be appended to any of the above to allow Projection to occur during no Ongoing Visit

```
on the "HOST_MONITORING" schema
```

Subject Monitoring Visit Item

Record Query for Item

```
And the "Subject Visit Item" is configured with "Monitoring Item Query"
| Property | Value |
| Visit No | {VISIT1 Visit No} |
| Monitoring Item | {Monitoring Item 1} |
| Entry No | {Sub3 Entry No} |
| Subject Visit | SCREEN1 |
| Data Monitoring Item Query | This is a sample query recorded |
```

Centres

Creating a Centre

```
Given a "new Reference Centre" exists, identified as "Centre1", configured as
 Property
                              Value
 Centre Address Line 1
                              | 4 Floor
                              | Hollywood road
 Centre Address Line 2
 Centre Address Line 3
                              | Bart Street
                              Solihull
 Centre Address Line 4
 Centre Province State County | West Midlands
 Centre Zip Code
                              B5 4UA
| Centre Country Code
                              {Default Country Code}
```

Associating Clinical Personnel to a Centre

```
And multiple Reference Clinical Personnel are associated or de-associated to centre "{CEN2 Centre No}" | Reference Clinical Personnel | Action | | CLP4 | remove | | CLP8 | add | | CLP5 | remove | | CLP9 | add |
```

Clinical Personnel

Creating a Reference Clinical Personnel

```
Given a " new Reference Clinical Personnel " exists, identified as " CLP4 ", configured as
 Property
                             | Value
 Potential Investigator Flag
                              Ν
 Title
                              Master
                             | Henry
 First Name
Middle Name
                             Adam
Surname
                            | Bannerly {time}
Suffix
                            CPD
 Email Address
                             hab@cpd.com
Phone Number
                            43534543
```

Associating a Clinical Personnel to a Centre
 Given the Reference Clinical Personnel "CLP4" is associated with centre "{CEN1 Centre No}"

Company Personnel

Creating a Company Personnel in Reference

Updating Company Personnel

Use the following to update a Company Personnel in Reference

```
And the "Reference Company Personnel", "REFPER6", is updated with
| Property | Value |
| Discontinued | Y |
```

Adding/Updating an Address to a Company Personnel in Reference

To add an Address to a Company Personnel use

```
Given a "new Reference Company Personnel Address" exists for personnel "REFPER1", identified as "Address2",
 Property
                       Value
 Primary Indicator
                       l N
 Address Type Code
                       | {blank}
                       Bangalore
 Town City
 Zip Code
                       500084
                      | Bangalore Address 1
 Address Line 1
 Address Line 2
                       | Bangalore Address 2
                       | Bangalore Address 3
 Address Line 3
                       | Bangalore Address 4
 Address Line 4
 Country Code
                       | {Trial Country Code}
 Province Country Code | KA
 Province State County | Karnataka
```

Once an Address has been added then it can be updated

Creating a Browser Set for a Personnel

This will create a Browser Set for a recently created Company Personnel. The Browser set will be set to list all Trials for a single Project

```
Given the "PER2" has a Browser Set configured
```

Field Hiding

Allow Field to be configured as "in use" or "not in use"
 This will allows a field to be marked as "in use" or "not in use" for all pages associated with a function

```
Given "Azure User Object ID" is configured as "in use" on all pages for function "IWF9042"
```

Note: If this step is used to mark the same field as "in use" and "not in use" in different scenarios there is the possibility that these could be executed at the same time so one of the scenarios could randomly fail.

Countries in Reference

This will generate a new Country in Reference which has a unique Country Code.

```
And a "new Reference Country" exists
And a "new Reference Country" exists, identified as "New"
```

The following Scenario Data will be created

Note: For WebApp/UI the new Country is generated with the name Auto_Country{time} so that it is deleted during database cleanup.

If this is implemented for Services then a different Name format should be used and also deleted during database cleanup.

General Windows handling

Alerts

In order to check that an Alert has been displayed

```
Then the user "is" notified with following alert message in the "Browser" page | I25301 - You have outstanding tasks. Please visit 'Tasks' for more information |
```