

Visits and Protocols

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Goal for Today

Demonstrate experimental features that enable native support for longitudinal studies and provide fine-grained validation to help manage data.

Scenario – PI has a new Study

- Study runs for 5 years
- Subjects return for regular visits every 6 months
- Baseline is a standard suite of tests and surveys
- Subjects get a PET-FDG at every visit
- If a subject shows signs of disease, they get a PET-PIB at each visit from then on
- If a subject dies, they get a pathology report

2 Years of Visits Illustrated

	Baseline	6 Mo	1 Yr	1.5 Yr	2 Y	
Chris	Baseline	Standard	Standard	Standard	Standard	
Pat	Baseline	Standard	Disease	Disease	Disease	
Sam	Baseline	Standard	Standard	Pathology		
Terry	Baseline	Standard	Standard	Standard	Disease	

PI Says

- I'm tragically disorganized. Help me...
 - Report missed visits
 - Know if data is missing from a visit
 - See if someone with disease didn't get the second PET
 - “Close” a visit once all data is there so we don't accidentally add more to it
 - Remember not to call someone back if they have a pathology report

Let's Break This Down

- Visits
 - Longitudinal Study
 - Each subject is seen 2x's a year for 5 years
 - Total of 10 Visits
- Visit Types
 - Baseline visit is a standard suite of tests
 - Each visit after could be of one of the following:
 - Standard Follow-Up
 - Follow-Up with Disease
 - Pathology

Visit Names vs. Visit Types

VISIT NAME

Baseline 6 Mo 1 Yr 1.5 Yr 2 Y

Chris	Baseline	Standard	Standard	Standard	Standard
Pat	Baseline	Standard	Disease	Disease	Disease
Sam	Baseline	Standard	Standard	Pathology	
Terry	Baseline	Standard	Standard	Standard	Disease

VISIT TYPE

The Protocol Framework Module:

- Native support for longitudinal studies within projects via Visits
- Strict definition of Visits
 - When a visit is expected (baseline, 6 mo, 1 yr) (delta)
 - What type of visit is allowed (No Disease / Disease)
 - Within each type, what kind of data is expected/required
- Enhanced User Interfaces
- Reporting and Acknowledgement

UI Example – Subject Details

Gender
Handedness
Group SALLY1

Upload Images
Download XML
Email
Manage Files
Delete

Visits & Experiments

Unsorted Experiments

Date	Experiment	Project	Label	Protocol	Move to Visit
2006-12-14	MR Session	SALLY	SALLY1_MR1		visit ▾

v0 **Open** baseline visit 1901-01-02 inHospital

Date	Experiment	Project	Label	Protocol
2006-12-14	MR Session	SALLY	SALLY1_MR1	

The following experiments are missing from this visit:

Missing	Create clin:vitalsData	Optional
---------	------------------------	----------

v1 **Open** second visit 1904-02-03 inHospital

Date	Experiment	Project	Label	Protocol
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This visit has no valid experiments

The following experiments are missing from this visit:

Missing	Create MR Session	Required
Missing	Create clin:vitalsData	Optional

v2 **Required** third visit [Create Visit +](#)

Click Create Visit above to start this subject's v2 visit

v3 **Required** third visit [Create Visit +](#)

Click Create Visit above to start this subject's v3 visit

UI Example – Subject Details

A Subject's V0 (baseline) Visit

Open/Closed

Date

Type

Edit and Delete Visit

Date	Experiment	Project	Label	Protocol
1901-01-02	baseline visit			
2006-12-14	MR Session	SALLY	SALLY1_MR1	

The following experiments are missing from this visit:

Missing	Create clin:vitalsData	Optional
---------	------------------------	----------

Missing Experiments List
(click to create if user creatable)

Valid Experiments List
(click the link to view/edit)

Required Experiment?

Remove Experiment from Visit

UI Example – Subject Details

A Subject's Unsorted Experiments

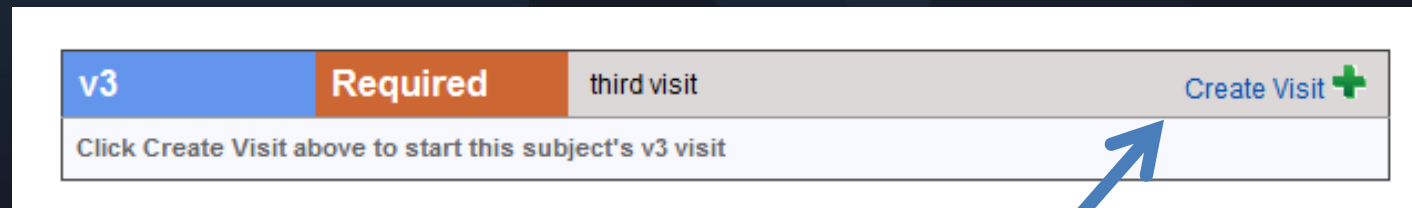
Unsorted Experiments					
Date	Experiment	Project	Label	Protocol	Move to Visit
2006-12-14	MR Session	SALLY	SALLY1_MR1		visit ▼



Use this to assign an experiment to a Visit

UI Example – Subject Details

A Visit That doesn't yet exist



The screenshot shows a horizontal bar with four segments: a blue segment with 'v3', an orange segment with 'Required', a grey segment with 'third visit', and a light blue segment with 'Create Visit +'. Below the bar is a white box containing the text 'Click Create Visit above to start this subject's v3 visit'. A blue arrow points from the text below to the 'Create Visit +' button.

Click here to create a “V3” Visit

Details

- Visit Name Definition (intervals)
 - Required
 - Delta
 - What visit types are valid for this time point
- Visit Type Definition
 - List of valid experiment types
 - Which experiments are required/optional
 - How those experiments are entered in the system
 - Ability to distinguish between identical experiment types that within a visit (PET-PIB / PET-FDG)

Features

- Open/Close a Visit (data entry)
- Ability to modify the Protocol as things change
- Able to deal with data that is outside the protocol (invalid visits, experiments that don't quite fit)

How to Use Protocols/Visits

- Install the Module
- Define Protocol and code it in JSON
- Upload the Protocol to the Project
- Use XNAT
- Change Protocol and Upload it again...

BOGUS Example

- Baseline Visit
 - 3T MR
 - PET-FDG
 - EGO Master 3.7
 - NIH Stroke Scale
- One Year Follow-Up
 - 3T MR
 - EGO Master 3.7
 - NIH Stroke Scale

- 2 Visit Types
- 2 Visits
- Simple Protocol,
Let's define it

Visit Type Parameters

- Name
- Description
- List of Expected Experiments
 - Type
 - XNAT Type for example, `xnat:mrSessiondata`
 - Protocol
 - poorly named... used to distinguish between experiments of the same type. In our first example, this is how you distinguish between PET-FDG and PET-PIB within one visit.
 - User Entered?
 - Create/Edit/Delete Link Template
 - Required?
 - Sort Order

Visit Type Definition #1 – Full Visit

- Name: Full Visit
- Description: Full Visit with PET
- Experiments List:
 - 3T MR
 - Type: xnat:Mrsessiondata
 - Protocol: null
 - Required: true
 - Sort order: 1
 - User entered: false
 - PET- FDG
 - Type: xnat:petsessiondata
 - Protocol: null
 - Required: true
 - Sort order: 2
 - User entered: false
 - EGO Master 3.7
 - Type: bogus:egoMaster
 - Protocol: null
 - Required: true
 - Sort order: 3
 - User entered: false
 - NIH Stroke Scale
 - Type: xnatx:.nihStrokeScaleData
 - Protocol: null
 - Required: true
 - Sort order: 4
 - User entered: true

Visit Type Definition #2 – NO PET

- Name: No Pet
- Description: No PET visit
- Experiments List:
 - 3T MR
 - Type: xnat:Mrsessiondata
 - Protocol: null
 - Required: true
 - Sort order: 1
 - User entered: false
 - EGO Master 3.7
 - Type: bogus:egoMaster
 - Protocol: null
 - Required: true
 - Sort order: 2
 - User entered: false
 - NIH Stroke Scale
 - Type: xnatx:.nihStrokeScaleData
 - Protocol: null
 - Required: true
 - Sort order: 3
 - User entered: true

Let's Define BOGUS' Visit Names (Intervals)

Name	Description	Delta	Allowed Visit Type List
V00	Baseline Visit	0	["Full Visit"]
V01	Follow-up Visit	365	["No Pet Visit"]

BOGUS Protocol Complete

- Visit Types
 - Full Visit
 - List of experiments
 - No PET
 - List of experiments
- Visit Names
 - Baseline
 - Only 1 allowed type – Full Visit
 - 1 Year Follow-Up
 - Only 1 allowed type – No PET Visit

BOGUS Protocol - JSON

JSON is a human & machine readable text file format used for data exchange. Used as a more compact alternative to XML.

```
{ "projectID": "BOGUS_OUA",  
  "versionDescription": "InitialProtocol",  
  "visitTypes": [  
    ...  
  ],  
  "visitNames": [  
    ...  
  ]  
}
```

Experiment definitions for each type of visit go here

Standard Visit, Drug Visit

Intervals like Baseline and Follow-Up and what Visit Types are allowed go here

Ex. Baseline 6Mo 1Y

BOGUS Protocol – JSON Continued

```
"visitTypes": [  
  {  
    "name": "baselineType",  
    "description": "Baseline Visit Type",  
    "expectedExperiments": [  
      {  
        "type": "xnat:mrSessionData",  
        "protocol": null,  
        "createLink": null,  
        "deleteLink": null,  
        "editLink": null,  
        "required": true,  
        "sortOrder": 0,  
        "userEntered": false  
      },  
      {  
        "type": "xnat:petSessionData",  
        ...  
      }  
    ]  
  }  
]
```

Upload the JSON

- PUT to the REST API:
 - /projects/BOGUS/protocols/protocol
 - (JSON and Format is validated on PUT)
- GET to view the JSON
- DELETE to the same URI to delete protocol
- PUT a new JSON file to update
 - History is maintained and viewable using the Configuration REST API...

Planned Features

- “Spreadsheet” type reporting to get a project-wide view of your project’s progress
- Warnings when data is outside protocol
- Issue tracking and Acknowledgement to indicate why something is outside protocol (suppresses future warnings)
- Fine-grained rules engine to support things like out-of-order visit types and pretty much anything you can imagine (scheduling?)
- Directed Path to simplify data creation

Any Questions?

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XNAT Discussion Google Group

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Let's Demo!

<http://wiki.xnat.org> – search for “Visits and Protocols”

or go to:

<https://wiki.xnat.org/display/Workshop2012Pub/Visits+and+Protocols+-+Jordan+Woerndle>