REDCap under FHIR
Enhancing electronic data capture with FHIR capability

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09 August 2017
Rationale

• Clinical Research (CR) play a pivotal role in health care delivery

• Funding bodies mandated sharing of CR data to exploit resulting increase in productivity & efficiency
  • Promote evidence-based medicine
  • Reduce costs of CR

• Efficient sharing of data necessitates data encapsulated with corresponding metadata

• Aim is to achieve *semantic interoperability* of clinical data
  • By normalising clinical data along similar metrics
  • By using terminologies to standardise the data across similar concepts

• Ultimately, we want to encourage secondary use of data.
Challenges with Clinical Study design

- Forms are often ill-conceived
- Free-text entry
- Data not normalised
- Poor use of controlled terminology to standardise meaning

.... tendency is to organise questions in a manner that befits the data capture process, not in a contextual manner ....
“REDCap is a mature, secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support data capture for research studies.”

http://project-redcap.org/

- Created by Vanberbilt University in 2004 (REDCap consortium created 2006)
- 2,473 active institutional partners across 113 countries
- > 439k projects supporting > 573k users

- Supports data capture via direct entry; branching logic; calculated fields
- Supports on demand reports & export to multiple formats (R, SAS, Excel, ODM)
### Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

**Legend for status icons:**
- **Incomplete**: No data saved
- **Verification**: Many statuses (all same)
- **Complete**: Many statuses (mixed)

#### Data Collection Instrument

| Patient Details | Status | Blood & POBT Results | Status | Blood & POBT Sample Result | Status | Questionnaire Findings | Status | Medications | Status | Indicator for Colonoscopy | Status | Family History of Cancer | Status | Colonoscopy Findings | Status | Colonoscopy Results | Status | Blood Analysis | Status | Cancer Staging | Status |
|-----------------|--------|-----------------------|--------|----------------------------|--------|-------------------------|--------|--------------|--------|--------------------------|--------|-------------------------|--------|------------------------|--------|-----------------------|--------|-----------------|--------|
| Patient Details | ![Status Icon] | Blood & POBT Results | ![Status Icon] | Blood & POBT Sample Result | ![Status Icon] | Questionnaire Findings | ![Status Icon] | Medications | ![Status Icon] | Indicator for Colonoscopy | ![Status Icon] | Family History of Cancer | ![Status Icon] | Colonoscopy Findings | ![Status Icon] | Colonoscopy Results | ![Status Icon] | Blood Analysis | ![Status Icon] | Cancer Staging | ![Status Icon] |

#### Data Collection Instrument

<table>
<thead>
<tr>
<th>Repeating Instruments</th>
<th>Status</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood &amp; POBT Sample Result</td>
<td>![Status Icon]</td>
<td>atorvastatin</td>
</tr>
<tr>
<td>Blood &amp; POBT Sample Result</td>
<td>![Status Icon]</td>
<td>ibertanin</td>
</tr>
</tbody>
</table>

#### Study ID:

- **Previous CRC?**: No
- **Other Cancer History?**: No
- **NBCSP?**: No
- **Smoker?**: Never
- **Colons?**: No
- **Ulcerative Colitis?**: No
- **Diabetes?**: No
- **Past Colonoscopy?**: Yes
- **Results?**: Polyps

#### Form Status

- **Complete?**: Incomplete

**Lock this record for this form?**

If locked, no user will be able to edit this record on this form until someone with Unlock privileges unlocks it.
The Fast Healthcare Interoperable Resource

• FHIR\(^1\) is a HL7 specification designed to facilitate the exchange of health-related information.
  • Specification defines a set of *minimalistic* and *generic* elements (80:20 rule)
    – Extensions are used to augment the content
  • Solutions built using snippets of *highly-focussed* data termed *resources*.
  • Modular design allows resources to be built and tested incrementally
  • Strong foundation in Web standards – XML, JSON, HTTP, RDF, etc
  • RESTful architecture that provides a rich set of operations
    – Create, Read, Update, Delete, Search, History, Transaction, Operation
    – Conditional Create, Update and Delete operations

\(^1\)http://hl7.org/fhir/index.html (STU3)
Why use Terminology Services?
Data capture using terminology lookup

• Enable FHIR lookup functionality in the *Modules Configuration* tab within the *Control Center* section in REDCap

• Enter the URL of a FHIR terminology service of your choice
Data capture using terminology lookup (2)
Terminology Lookup Definitions

- A Code System defines a set of codes with meanings
- A Value Set selects a set of codes from one or more code system
- A Reference Set is a standard format for maintaining and distributing a set of references to SNOMED CT components.
Data capture using terminology lookup (3)

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Panadeine uncoated tablet, 24 blister pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form Status</td>
<td></td>
</tr>
<tr>
<td>Complete?</td>
<td></td>
</tr>
<tr>
<td>Lock this record for this form?</td>
<td>If locked, no user will be able to edit this record on this form until someone with Lock/Unlock rights enters a new record ID.</td>
</tr>
</tbody>
</table>

Adding new Record ID 1

<table>
<thead>
<tr>
<th>Record ID</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Name</td>
<td>Panadeine uncoated tablet, 24 blister pack</td>
</tr>
<tr>
<td>Form Status</td>
<td>Incomplete</td>
</tr>
<tr>
<td>Complete?</td>
<td>Incomplete</td>
</tr>
</tbody>
</table>
Transforming REDCap forms to FHIR

Questionnaire

REDCap Form

Questionnaire Response

Patient

Form Section question

Form Section answer

Name Age Gender ...
FHIR Representation

Questionnaire Resource

```
{
  "resourceType": "Bundle",
  "id": "redcapFhirBundle",
  "type": "transaction",
  "entry": [
    {
      "fullUrl": "http://hl7.org/fhir/Questionnaire/my-first-instrument",
      "resource": {
        "resourceType": "Questionnaire",
        "id": "my-first-instrument",
        "status": "published",
        "item": [
          {
            "id": "my-first-instrument.record-id",
            "text": "My First Instrument",
            "type": "group",
            "repeats": false,
            "item": [
              {
                "id": "medications",
                "concept": [
                  {
                    "system": "http://snomed.info/sct?fhir_vs=refset",
                    "code": "929360051000036108",
                    "display": "CTPP"
                  }
                ],
                "text": "Medication Name",
                "type": "text",
                "required": false,
                "maxLength": 999
              }
            ]
          }
        ]
      }
    }
  ]
}
```

QuestionnaireResponse Resource

```
{
  "resourceType": "Bundle",
  "id": "redcapFhirBundle",
  "type": "transaction",
  "entry": [
    {
      "fullUrl": "http://hl7.org/fhir/QuestionnaireResponse/90703679-931b-45b5-af6e-dfe4e79355ae",
      "resource": {
        "resourceType": "QuestionnaireResponse",
        "identifier": {
          "id": "90703679-931b-45b5-af6e-dfe4e79355ae",
          "system": "urn:ietf:rfc:3986",
          "value": "my-first-instrument-2"
        },
        "questionnaire": {
          "reference": "Questionnaire/my-first-instrument"
        },
        "status": "in-progress",
        "subject": {
          "reference": "Patient/2"
        },
        "item": [
          {
            "LinkId": "medications",
            "answer": [
              {
                "valueCoding": {
                  "system": "http://snomed.info/sct",
                  "code": "19166011000036103",
                  "display": "Panadeine uncoated tablet, 12, blister pack"
                }
              }
            ]
          }
        ]
      }
    }
  ]
}
```
Benefits of capturing clinical research data in FHIR

• Achieve *symbolic* Artificial Intelligence
  • Data normalised along similar metrics
  • Use of terminology to standardise the meaning of the data

• Efficient traversal and querying of data

• Increased efficiency during data collection

• Leads to better data sharing

• Lays foundation for *reproducible clinical research* by providing adequate *metadata* and *context*.
Limitations of the approach

• Questionnaire and QuestionnaireResponse resources have limited querying functionality

• Simple queries can be performed
  • E.g. List all questions (items) that a participant has answered
  • Find the response to a question from a participant

• More complex queries cannot be answered.
  • Queries requiring the terminology hierarchy
    – E.g. Find all participants who have undergone a hip test
  • Queries that require calculations on the responses
    – E.g. Find all participants who have a sBP lower than 85
  • These queries require additional FHIR resources, e.g. Observation, Condition, Medication to facilitate their retrieval

• This represents future work and has been implemented by my colleague Alejandro Metke (FHIRCap)
Related Publications


Thank you ...

... Questions

Acknowledgements

Dr Jim Steel
Dr Michael Lawley
Dr Alejandro Metke
Mr Simon Gibson
Data capture using terminology lookup (2.5)

• Value Set lookup
  Base URL + “/ValueSet?_elements=name,url”

• Code System lookup
  Base URL + “/CodeSystem?_elements=name,valueSet”

• Reference Set lookup
  to obtain code for ref set, then,