CDISC Tech Webinar Series - TRANSFoRm Project, Biomedical Concepts, SHARE and the Semantic Web

10 NOV 2016
Agenda

• CDISC Tech Webinar
  ▪ TRANSFoRm Project
    • Vasa Curcin, Lecturer in Health Informatics, King’s College London
    • Stanisław Saganowski, Wrocław University of Science and Technology, Poland, Research Assistant
    • Piotr Bródka, Wrocław University of Science and Technology, Poland, Assistant Professor
    • Radosław Michalski, Wrocław University of Science and Technology, Poland, Assistant Professor
    • Brendan Delaney, TRANSFoRm Project
  ▪ Biomedical Concepts, SHARE and the Semantic Web
    • Iberson-Hurst, CEO, Assero

• CDISC Online Education & Event Updates
  ▪ John Ezzell, CDISC
Question & Answer

• ‘Panelist’: Question
OR
• ‘Presentation’: Question

Examples:

Vasa: How is ODM-XML used in other devices?
TRANSFoRm: Can you elaborate on future plans for your application?
Content Disclaimer

The CDISC Tech Series webinars are intended to showcase emerging technology that leverage CDISC standards. All content included in this presentation is for educational and informational purposes only. References to any specific commercial product, process, or service, or the use of any corporation name do not constitute endorsement, recommendation, or favoring by CDISC or the CDISC community.
TRANSFoRm Project: ODM-XML Extension in User Interface for Mobile Apps

Vasa Curcin¹, Stanisław Saganowski², Piotr Bródka², Radosław Michalski², Brendan Delaney³

¹Department of Primary Care and Public Health Sciences, King’s College London, United Kingdom
²Wroclaw University of Technology, Department of Computational Intelligence, Wrocław, Poland
³Faculty of Medicine, Department of Surgery & Cancer, Imperial College London, United Kingdom

This project has received funding from the European Union’s Seventh Framework Programme for research, technological development and demonstration under grant agreement no 247787 [TRANSFoRm]
Context for TRANSFoRm

• Clinical Research in crisis
  – Hard to identify subjects
  – Complex, costly Case Report Forms (CRFs) with duplicate data entry
  – Funding not cost-effective

• Diagnostic error
  – 60% of litigation claims against GPs (UK/EU/US)
  – Failure of Decision Support Systems for Diagnosis

• Common challenges in Europe and US
Defining functions of a LHS are to:
1. routinely and securely aggregate data from disparate sources
2. convert the data to knowledge
3. disseminate that knowledge, in actionable forms, to everyone who can benefit from it.
Data domains in the Learning Health System

Specific research data
- Clinical trials
- Controlled populations
- Well-defined questions

Routinely collected data
- EHR systems
- Wide coverage
- Vast quantity
- May lack in detail and quality

Actionable data
- Distilled scientific findings
- Usable in clinical practice
- Decision support
TRANSFoRm Project

• TRANSFoRm: EU FP7 funded project 2010-2015
• 21 partners, 10 EU member states
• Developing methods, models, services, validated architectures and demonstrations to support:
  – Epidemiological research using GP records, including genotype-phenotype studies and other record linkages
  – Clinical trials embedded in the EHR
  – Decision support for diagnosis

www.transformproject.eu
Model-driven data connectivity

- Clinical Research Information Model
- Study tool/CTMS
- Middleware
- Data node connector
- Semantic Mediator
- DB
- Study/Trial

Unified Structural/Terminological Interoperability Framework for Primary Care

- Clinical Data Integration Model
- Terminologies & mappings
- CDIM-DSM Mappings
- Data source model (DSM)

Ontology Editor
Model Instance Editors
Model-driven data connectivity

- Information model
- Conceptual backbone to all software in the project
Model-driven data connectivity

- Central information model
- Upper ontology: BFO
- Middle (domain) ontologies

Clinical Research Information Model → Study tool/CTMS → Middleware

- Data node connector
- Semantic Mediator
- DB

Unified Structural/Terminological Interoperability Framework for Primary Care

- Terminologies & mappings
- CDIM-DSM Mappings
- Data source model (DSM)

Ontology Editor

Model Instance Editors

Translational Research and Patient Safety in Europe
Model-driven data connectivity

- Local data descriptor
- Simple, developed by local users
Use case 2: GORD Clinical Trial

- PPI Rx consumers within last 12m, patients flagged prior to consultation
- PPI Rx at consultation
- Inclusion criteria for new reflux cases satisfied at consultation

GORD → PPI Rx
- On-demand
- Continuous

QoL = Self-rated Health (SRH), Short Form Health Survey (SF-12)
Symptoms = Reflux Disease Questionnaire (RDQ), GORD impact scale
Rx = PPI consumption
Alarms = unintentional weight loss, swallowing, anaemia

Scheduled (web questionnaire) and event-driven (eCRF/EHR)
GORD RCT workflow

- eCRFs (CROMs) filled by clinicians at weeks 0 and 8
  - Partially auto-filled from EHR, validated by GP
  - Web interface or EHR vendor-specific tool
- PROMs filled by patients at weeks 0 and 8
  - Mobile applications for Android and iPhone
- All collected data stored in the EHR system as well as the research database

Four countries:
- Poland
  - Asseco mMedica
- Greece
  - TransHIS
- Netherlands
  - TransHIS
- UK
  - InPS Vision
  - TPP SystmOne
eCRF elements retrieved from EHR

- The data elements need to have *computable* representations to support semantic interoperability, so that they can be retrieved from eHRs and populated into eCRFs.
  - Year of Birth
  - Gender
  - Height/Weight/BMI
  - Smoke
  - GORD diagnosis
  - PPI medication
  - H2-Blocker
  - Antacids
  - Upper endoscopy
  - Esophagitis/Barrett’s from endoscopy
  - Hp status
Semantic interoperability technologies used

- **OpenEHR Archetype Definition Language (ADL)** as the mechanism to define clinical data elements, bound to CDIM definitions
- **CDISC Study Data Model (SDM)** as the structure and workflow model for the study
- **CDISC Operational Data Model (ODM)** as the basis for data collection forms, extended to support:
  - Semantic interoperability with local eHR system.
  - Data collection in mobile environment
TRANSFoRm applications

Questionnaires

Pending

- **Reflux Disease Questionnaire**
  - Due date: 02.07.2015.

- **First Visit Continuous PROM**
  - Due date: 02.07.2015.

Completed

- **Reflux Disease Questionnaire**
  - Submit date: 02.07.2015.

- **First Visit Continuous PROM**
  - Submit date: 02.07.2015.

**Reflux Disease Questionnaire (RDQ)**

Thinking about your symptoms over the past 7 days, how would you rate the following?

1. A burning feeling behind your breastbone
   - Very mild

2. Pain behind your breastbone
   - Mild

3. A burning feeling in the centre of the upper stomach
   - Moderate

4. A pain in the centre of the upper stomach
   - Moderate

5. An acid taste in your mouth
   - Moderately severe

6. Unpleasant movement of material upwards

This project has received funding from the European Union’s Seventh Framework Programme for research, technological development and demonstration under grant agreement no 247787 [TRANSFoRm].
Problem

- Different UI controls available on Android, iOS and Web
- Different UI controls design across the same platform
- Users know only their devices
- Several types of questions in questionnaires
Problem

- paper version

- electronic version
Solution

- ODM extension which defines the UI solution for each question
- Additional attribute „QuestionType” added to „ItemDef” object
- Six predefined values:

<table>
<thead>
<tr>
<th>QuestionType</th>
<th>UI control name</th>
<th>Android component</th>
<th>iOS component</th>
<th>Web App component</th>
</tr>
</thead>
<tbody>
<tr>
<td>InputField</td>
<td>Input field</td>
<td>EditText</td>
<td>UITextField</td>
<td>input</td>
</tr>
<tr>
<td>DatePicker</td>
<td>Date picker</td>
<td>DatePicker</td>
<td>UIDatePicker</td>
<td>datepicker</td>
</tr>
<tr>
<td>RadioButton</td>
<td>Radio button</td>
<td>RadioButton</td>
<td>UITableView</td>
<td>radio</td>
</tr>
<tr>
<td>YesNo</td>
<td>Switch control</td>
<td>Switch</td>
<td>UISegmentedControl</td>
<td>radio</td>
</tr>
<tr>
<td>DropDown</td>
<td>Drop down list</td>
<td>Spinner</td>
<td>UITableView (on new screen)</td>
<td>radio</td>
</tr>
</tbody>
</table>
Predefined values

- Goal 1: satisfy Transform needs
- Goal 2: utilize user experience with his own mobile device
- Goal 3: keep standards persistent on each platform (Android, iOS, web)

- Users familiar with the interface and will know how to interact with it
- The same question may look different on each platform
- The same question may even look different on two Android devices
Input field

- Used for direct input from the keyboard

<table>
<thead>
<tr>
<th>Android</th>
<th>iOS</th>
<th>Web</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Information</td>
<td>Age Information</td>
<td>First name</td>
</tr>
<tr>
<td>1. Year of Birth</td>
<td>1. Year of Birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Month of Birth</td>
<td>2. Month of Birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Select birth day</td>
<td>3. Select birth day</td>
<td></td>
</tr>
</tbody>
</table>
Date picker

• Used to choose a date

Android

iOS

Web

3. Select birth day

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>Mar</td>
<td>15</td>
</tr>
<tr>
<td>2014</td>
<td>Kwi</td>
<td>16</td>
</tr>
<tr>
<td>2015</td>
<td>Maj</td>
<td>17</td>
</tr>
</tbody>
</table>

3. Select birth day

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>lutego</td>
<td>14</td>
</tr>
<tr>
<td>2013</td>
<td>marca</td>
<td>15</td>
</tr>
<tr>
<td>2014</td>
<td>kwietnia</td>
<td>16</td>
</tr>
<tr>
<td>2015</td>
<td>maja</td>
<td>17</td>
</tr>
<tr>
<td>2016</td>
<td>czerwca</td>
<td>18</td>
</tr>
</tbody>
</table>

Year of Birth must be more than 1900
Radio button

- used to select only one option among many available

### Android

1. In general, would you say your health is:
   - [ ] Excellent
   - [x] Very good
   - [ ] Good
   - [ ] Fair
   - [ ] Poor

### iOS

1. In general, would you say your health is:
   - [ ] Excellent
   - [x] Very good
   - [ ] Good
   - [ ] Fair
   - [ ] Poor

### Web

<table>
<thead>
<tr>
<th>Very Good</th>
<th>Good</th>
<th>Neither good nor poor</th>
<th>Poor</th>
<th>Very poor</th>
</tr>
</thead>
</table>

Switch control

- Two options available, user selects only one

### Android

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

1. Accomplished less than you would like
   - [ ] Yes
   - [ ] No

2. Were limited in the kind of work or other activities
   - [ ] No

### iOS

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

1. Accomplished less than you would like
   - [ ] No
   - [ ] Yes

2. Were limited in the kind of work or other activities
   - [ ] No
   - [ ] Yes

### Web
Drop down list

• A list is shown to the study participant, only one element can be selected

**Android**

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..

1. Have you felt calm and peaceful?

   Select value

   - All of the time
   - Most of the time
   - A good bit of the time
   - A little of the time
   - None of the time

**iOS**

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks..

1. Have you felt calm and peaceful?

   - All of the time
   - Most of the time
   - A good bit of the time
   - A little of the time
   - None of the time

2. Did you have a lot of energy?

3. Have you felt downhearted and blue?

**Web**

<table>
<thead>
<tr>
<th>Very Good</th>
<th>Good</th>
<th>Neither good nor poor</th>
<th>Poor</th>
<th>Very poor</th>
</tr>
</thead>
</table>

29
11.2 Self-rated health

How would you rate your general health status?

- Very good
- Good
- Neither good nor poor
- Poor
- Very poor

State of being

- Very Good
- Good
- Neither good nor poor
- Poor
- Very poor
3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Accomplished less than you would like
b. Were limited in the kind of work or other activities
2. Thinking about your symptoms over the past 7 days, how would you rate the following?

<table>
<thead>
<tr>
<th></th>
<th>Did not have</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Moderately severe</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. A burning feeling behind your breastbone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Pain behind your breastbone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. A burning feeling in the centre of the upper stomach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. A pain in the centre of the upper stomach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Accomplished less than you would like

b. Were limited in the kind of work or other activities
Missing „QuestionType” attribute

• if ItemDef contains attribute DataType=„date”, then QuestionType=„DatePicker”,

• else if ItemDef contains a CodeListRef tag, then QuestionType=„DropDown”

• else QuestionType=„InputField”.
2. Thinking about your symptoms over the past 7 days, how would you rate the following?

<table>
<thead>
<tr>
<th>Did not have</th>
<th>Very mild</th>
<th>Mild</th>
<th>Moderate</th>
<th>Moderately severe</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. A burning feeling behind your breastbone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Pain behind your breastbone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. A burning feeling in the centre of the upper stomach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. A pain in the centre of the upper stomach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A burning feeling behind your breastbone

- Very mild

Pain behind your breastbone

- Mild

A burning feeling in the centre of the upper stomach

- Moderate

An acid taste in your mouth

- Severe

Unpleasant movement of material upwards from the stomach

- Moderately severe
„QuestionType” attribute misuse

• It is the study designers’ responsibility to use „QuestionType” attribute properly.
• In case of inappropriate use the eCRF might be rendered incorrectly.
Conclusions

• Decide beforehand
• Chose proper number of QuestionTypes
• Make documentation!
Discussion

• How to avoid extending extension?
• How to handle new UI element?
Questions?

Jankowski J., Saganowski S., Bródka P.: *Evaluation of TRANSFoRm mobile eHealth solution for remote patient monitoring during clinical trials.*

[www.hindawi.com/journals/misy/2016/1029368](http://www.hindawi.com/journals/misy/2016/1029368)

[www.transformproject.eu](http://www.transformproject.eu)
CDISC Members Only Webinar
Biomedical Concepts, SHARE and the Semantic Web

10th November 2016
Dave Iberson-Hurst, Assero Ltd

Version 1
Our World Is a Very Big Graph
... Then We Make Life Hard
Our Standards Are Views
And Structure …

Tabular structure used for transport, storage and presentation

Presentation

Data

Transport Format

Transport
So …
**Protocol**

- Measurement of vital signs (heart rate, blood pressure at rest)

**Protocol dictates capture of Blood Pressure (DIABP + SYSBP)**

**Protocol IE criteria could also use RCs**

**Statistical Analysis Plan**

**Protocol dictates capture of Blood Pressure (DIABP + SYSBP)**

**Protocol IE criteria could also use RCs**

**Statistical Analysis Plan**

---

### CRF

<table>
<thead>
<tr>
<th>Position</th>
<th>Diastolic</th>
<th>Units</th>
<th>Systolic</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mmHg</td>
<td></td>
<td>mmHg</td>
</tr>
</tbody>
</table>

**Correct mapping PLUS Traceability**

**Set the correct test code**

**Shared terminology for response:** SITTING, STANDING, SUPINE, …

---

**Diagram Details**

- **CRF Capturing DIABP**
- **Tabulation**
- **Protocol**
- **Shared terminology for response:** SITTING, STANDING, SUPINE, …
Demonstration

- Terminology
- Biomedical Concepts
- Forms
- SDTM Models, IGs, Domains
And Iterate …

We cannot build everything in one go. We need to build piece-by-piece, day-by-day, with a clear plan of where we want to go and allow today’s world and tomorrow’s world to co-exist.

• Iterate
• Learn
• Adjust
• Repeat
One Step?
Next Step?

A = B - C
Summary

• Semantic web in action, linked [meta]data
• SHARE exports used to build our world
• Biomedical Concepts used to build an underlying data layer
Contact And More Information

Email
dave.iberson-hurst@assero.co.uk

Further Information Available At
www.assero.co.uk

Links, links and more links

Having had many discussion about linked (meta)data and the semantic web at the CDISC Interchange in the US and the PhUSE conference in Barcelona I thought this may be useful for those who don’t quite see what all the fuss is about. A short video using the Glandon MDR to show the benefits of linked data when... Continue reading...
CDISC Online Education & Event Updates

John Ezzell, CDISC
# Upcoming Webinars

<table>
<thead>
<tr>
<th>Presenter</th>
<th>Topic</th>
<th>Webinar Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Shannon Labout, CCDM, Vice President of Education, CDISC</td>
<td>CDISC Members Only Mini-Training: Comparing CDASH &amp; SDTM: Why are There Two Standards?</td>
<td>14 NOV 2016</td>
</tr>
<tr>
<td>• Kit Howard, Director of Education, CDISC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Gary Walker, Associate Director, Statistical Programming, Quintiles</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Webinar details and registration at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*
Standard currently out for review

- New Draft Ebola v1 Now Available for Public Review
  Comments Due by: 11 November 2016

- New Draft Malaria Therapeutic Area User Guide v1 Now Available for Public Review
  Comments Due by: 11 November 2016

- New Draft Japanese Translation of SDTM v1.4 Now Available for Public Review
  Comments Due by: 30 November 2016

- New Draft Prostate Cancer Therapeutic Area User Guide v1.0 Now Available for Public Review
  Comments Due by: 8 December 2016
### UPCOMING NORTH AMERICA PUBLIC COURSES

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered:</th>
<th>Discount period ends:</th>
<th>Late fees kick(ed) in:</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miami, FL</td>
<td>23-27 Jan 2017</td>
<td>SDTM, CDASH, ADaM Primer, ADaM T&amp;A</td>
<td>23 Oct 2016</td>
<td>23 Dec 2106</td>
<td></td>
</tr>
<tr>
<td>Raleigh, NC</td>
<td>27 Feb – 3 Mar 2017</td>
<td>SDTM, CDASH, ADaM Primer, ADaM T&amp;A</td>
<td>28 Nov 2016</td>
<td>28 Jan 2017</td>
<td></td>
</tr>
<tr>
<td>Audubon, PA</td>
<td>3-7 Apr 2017</td>
<td>SDTM, CDASH, ADaM Primer, ADaM T&amp;A, CT, Define-XML</td>
<td>3 Jan 2017</td>
<td>3 Mar 2017</td>
<td></td>
</tr>
<tr>
<td>Toronto, ON</td>
<td>5-9 June 2017</td>
<td>SDTM, CDASH, ADaM Primer, ADaM T&amp;A, Define-XML</td>
<td>6 Mar 2017</td>
<td>5 May 2017</td>
<td></td>
</tr>
</tbody>
</table>

Visit [cdisc.org/public-courses](https://cdisc.org/public-courses) for information on other CDISC Public Training events.
## UPCOMING EUROPE PUBLIC COURSES

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered:</th>
<th>Discount period ends</th>
<th>Late fees kick(ed) in:</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>London, UK</td>
<td>24-28 Apr 2017</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>CDISC</td>
</tr>
<tr>
<td>Frankfurt, Germany</td>
<td>19-23 Jun 2017</td>
<td>SDTM, CDASH, Define-XML, ADaM</td>
<td>20 Mar 2017</td>
<td>20 May 2017</td>
<td>CLINIPAGE WORLDWIDE</td>
</tr>
</tbody>
</table>

Visit [cdisc.org/public-courses](http://cdisc.org/public-courses) for information on other CDISC Public Training events.
# UPCOMING ASIA PUBLIC COURSES

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Discount period ends</th>
<th>Late fees kick(ed) in</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyderabad, India</td>
<td>11-14 Dec</td>
<td>CDISC Overview, SDTM, CDASH</td>
<td>Ended</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Tokyo, Japan</td>
<td>13-17 Mar 2017</td>
<td>SDTM, CDASH, ADaM, Define-XML</td>
<td>TBD</td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>

Visit [cdisc.org/public-courses](cdisc.org/public-courses) for information on other CDISC Public Training events.
CDISC Online Training Production Update

- Just Released
  - ADaM Module 4 Online Training
  - Mini-Training: Ensuring USUBJID is Unique for an Individual in an Application
Any more questions?

Thank you for attending this webinar.

CDISC’s vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research
CDISC Members Drive Global Standards

Thank you for your support!