# semantics driven applications

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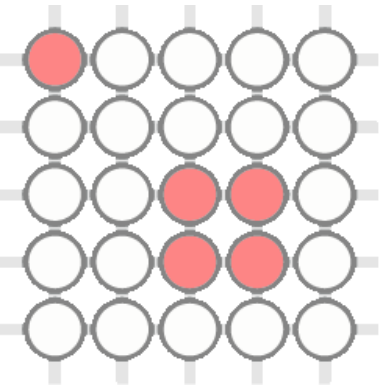
It commonly happens that there is no one conclusive study but 'meta-analysis' gives you a combined result from every randomised trial that has been done around the world. For example, the drug Tamoxifen  an oestrogen blocker that may prevent breast cancer cells growing  was the object of forty-two studies world-wide  of which only four or five had shown significant benefits. But this did not mean that Tamoxifen did not protect against breast cancer. 'When we put all the studies together it was blindingly obvious that it does  you don't have to be a medical statistician to see that. Nor do you need to be an economist to see the advantages of saving tens of thousands of lives with this inexpensive drug'

Prof. Richard Gray, University of Birmingham

# cancergrid

- not just about cancer
- definitely not a computing grid
- a project to develop tools for
  - semantic annotation of clinical trials
  - generation of trial data management software
  - tooling for meta-analysis



cancergrid

# software engineering @ oxford

- part of the department of computer science
- teaching and research in all matters of software engineering
  - from human factors
  - to software engineering mathematics
  - for professional software engineers
- oxford metadata group
  - dedicated to research into semantic frameworks
  - develop open source tooling for medical research

# META-ANALYSIS

# early breast cancer trialists' collaborative group

- initiated in 1983
- hundreds of institutions worldwide
- consensus on 30 variables, a data model and submission format – now increasing to 200 variables
- analyse data every 5 years
- computable data and follow-up for 200,000 cases in the 2000 review
- rock-solid evidence base for the treatment of early breast cancer

# doesn’t always work

- systematic review of TP53 and Platinum response
  - 75 clinical studies
  - 8331 patients
  - prognostic value of TP53 mutation in ovarian cancer
  - no conclusions could be drawn
    - most of the study metadata was missing
    - insufficient detail about the IHC
    - only some exons sequenced

# why?

- not enough metadata – especially identifiers
- not enough data standards – incompatible representations
- not enough data management – data captured only for original purpose

# FORMS AND DATASET REGISTRATION

**Refine your search here or Start Over.**

Expert Search

Change your search with any or all of the fields below.
Search within your current results by adding more search terms.

Search Terms: prostate — Search — Help

Recruitment: All Studies

Study Results: All Studies

Study Type: All Studies

Targeted Search:

Conditions:

Interventions: radiotherapy

Outcome Measures:

Lead Sponsors: — Exact Match

Sponsors: — Exact Match

Study IDs:

Locations:

State 1: --- Optional ---

Country 1: --- Optional ---

State 2: --- Optional ---

Country 2: --- Optional ---

State 3: --- Optional ---

Country 3: --- Optional ---

Location Terms:

Additional Criteria:

## Found 382 studies with search of: prostate | radiotherapy

Hide studies that are not seeking new volunteers.

Display Options

| Rank | Status | Study |
|---|---|---|
| 1 | Recruiting | The ELDORADO (Eligard®, Docetaxel and Radiotherapy) Study<br>Condition: Prostatic Neoplasms<br>Interventions: Drug: Docetaxel; Drug: Leuprolide Acetate (Eligard®); Radiation: Intensity-Modulated Radiotherapy |
| 2 | Active, not recruiting | A Phase III Intensity Radiotherapy Dose Escalation for Prostate Cancer Using Hypofractionation<br>Condition: Prostate Cancer<br>Interventions: Radiation: Conventional Fractionated Intensity Modulated Radiotherapy; Radiation: Hypofractionated Intensity Modulated Radiotherapy |
| 3 | Recruiting | Radiation Therapy With or Without Androgen-Deprivation Therapy in Treating Patients With Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Drug: bicalutamide; Drug: buserelin; Drug: flutamide; Drug: goserelin acetate; Drug: leuprolide acetate; Drug: triptorelin; Radiation: 3-dimensional conformal radiation therapy; Radiation: intensity-modulated radiation therapy |
| 4 | Active, not recruiting | MRI-Guided Placement of Imaging Markers in Patients With Prostate Cancer Undergoing External-Beam Radiation Therapy<br>Condition: Prostate Cancer<br>Interventions: Procedure: implanted fiducial-based imaging; Procedure: magnetic resonance imaging; Radiation: 3-dimensional conformal radiation therapy; Radiation: external beam radiation therapy; Radiation: radiation therapy treatment planning/simulation |
| 5 | Active, not recruiting | Internal Radiation Therapy With or Without External-Beam Radiation Therapy in Treating Patients With Localized Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Radiation: brachytherapy; Radiation: hypofractionated radiation therapy; Radiation: image-guided radiation therapy; Radiation: intensity-modulated radiation therapy |
| 6 | Recruiting | Radiation Therapy in Treating Patients Receiving Hormone Therapy for Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Radiation: 3-dimensional conformal radiation therapy; Radiation: intensity-modulated radiation therapy |
| 7 | Completed | Radical Radiotherapy by External Beam Radiation Versus Radical Radiotherapy With Temporary Iridium Implant Plus External |

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Home | Search | Study Topics | Glossary

Search

Study 2 of 382 for search: prostate | radiotherapy

Previous Study | Return to Search Results | Next Study

Full Text View | Tabular View | No Study Results Posted | Related Studies

A Phase III Intensity Radiotherapy Dose Escalation for Prostate Cancer Using Hypofractionation

This study is ongoing, but not recruiting participants.

Study NCT00667888 Information provided by M.D. Anderson Cancer Center
First Received: April 24, 2008 Last Updated: September 29, 2010 History of Changes

## Tracking Information

| | |
|---|---|
| First Received Date ICMJE | April 24, 2008 |
| Last Updated Date | September 29, 2010 |
| Start Date ICMJE | January 2001 |
| Estimated Primary Completion Date | January 2013 (final data collection date for primary outcome measure) |
| Current Primary Outcome Measures ICMJE (submitted: January 4, 2010) | Number of Patients with Incidence of Rising PSA [ Time Frame: PSA every 3 months for the first 2 years; every 6 months for years 3-5; and yearly thereafter ] [ Designated as safety issue: Yes ] |
| Original Primary Outcome Measures ICMJE (submitted: April 25, 2008) | The goal is to compare using external beam radiotherapy with intensity modulated beams for fewer days at a higher dose per day to the same type of therapy for more days at a lower dose per day in the treatment of prostate cancer. [ Time Frame: 12 Years ] [ Designated as safety issue: No ] |
| Change History | Complete list of historical versions of study NCT00667888 on ClinicalTrials.gov Archive Site |
| Current Secondary Outcome Measures ICMJE | |
| Original Secondary Outcome Measures ICMJE (submitted: April 25, 2008) | The safety of these treatments will also be studied and compared. [ Time Frame: 12 Years ] [ Designated as safety issue: Yes ] |

## Descriptive Information

**Found 122 studies with search of: "Prostatic Diseases" | radiotherapy | NIH OR NCI**

Hide studies that are not seeking new volunteers.

Display Options

| Rank | Status | Study |
|---|---|---|
| 1 | Active, not recruiting | MRI-Guided Placement of Imaging Markers in Patients With Prostate Cancer Undergoing External-Beam Radiation Therapy<br>Condition: Prostate Cancer<br>Interventions: Procedure: implanted fiducial-based imaging; Procedure: magnetic resonance imaging; Radiation: 3-dimensional conformal radiation therapy; Radiation: external beam radiation therapy; Radiation: radiation therapy treatment planning/simulation |
| 2 | Active, not recruiting | Amifostine to Protect the Rectum During External Beam Radiotherapy for Prostate Cancer<br>Condition: Prostatic Neoplasms<br>Interventions: Drug: Amifostine trihydrate; Radiation: radiation therapy |
| 3 | Completed | Radiation Therapy With or Without Vaccine Therapy in Treating Patients With Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Biological: aldesleukin; Biological: recombinant fowlpox-prostate specific antigen vaccine; Biological: recombinant vaccinia prostate-specific antigen vaccine; Biological: recombinant vaccinia-B7.1 vaccine; Biological: sargramostim; Radiation: brachytherapy; Radiation: radiation therapy |
| 4 | Recruiting | MRI-Guided Radiation Therapy in Treating Patients With Prostate Cancer<br>Condition: Prostate Cancer<br>Intervention: Radiation: radiation therapy |
| 5 | Recruiting | MRI-Guided Radiation Therapy in Treating Patients With Prostate Cancer<br>Condition: Prostate Cancer<br>Intervention: Radiation: radiation therapy |
| 6 | Active, not recruiting | Internal Radiation Therapy With or Without External-Beam Radiation Therapy in Treating Patients With Localized Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Radiation: brachytherapy; Radiation: hypofractionated radiation therapy; Radiation: image-guided radiation therapy; Radiation: intensity-modulated radiation therapy |
| 7 | Recruiting | Radiation Therapy With or Without Androgen-Deprivation Therapy in Treating Patients With Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Drug: bicalutamide; Drug: buserelin; Drug: flutamide; Drug: goserelin acetate; Drug: leuprolide acetate; Drug: triptorelin; Radiation: 3-dimensional conformal radiation therapy; Radiation: intensity-modulated radiation therapy |
| 8 | Recruiting | Samarium Sm 153 Lexidronam Pentasodium and 3-Dimensional Conformal Radiation Therapy or Intensity-Modulated Radiation Therapy in Treating Patients With Rising Prostate-Specific Antigen Levels After Radical Prostatectomy for Prostate Cancer<br>Condition: Prostate Cancer<br>Interventions: Radiation: 3-dimensional conformal radiation therapy; Radiation: intensity-modulated radiation therapy; Radiation: samarium Sm 153 lexidronam pentasodium |
| 9 | Active, not recruiting | Radiation Therapy in Treating Patients With Stage II Prostate Cancer<br>Condition: Prostate Cancer |

# Radiation Therapy in Treating Patients With Stage II Prostate Cancer

**This study is ongoing, but not recruiting participants.**

Study NCT00331773 Information provided by National Cancer Institute (NCI)
First Received: May 30, 2006 Last Updated: December 17, 2009 History of Changes

## Tracking Information

| | |
|---|---|
| **First Received Date** ICMJE | May 30, 2006 |
| **Last Updated Date** | December 17, 2009 |
| **Start Date** ICMJE | April 2006 |
| **Estimated Primary Completion Date** | May 2011 (final data collection date for primary outcome measure) |
| **Current Primary Outcome Measures** ICMJE (submitted: December 25, 2007) | Disease-free survival at 5 years as measured by Kaplan-Meier [ Designated as safety issue: No ] |
| **Original Primary Outcome Measures** ICMJE (submitted: November 9, 2006) | Disease-free survival at 5 years as measured by Kaplan-Meier |
| **Change History** | Complete list of historical versions of study NCT00331773 on ClinicalTrials.gov Archive Site |
| **Current Secondary Outcome Measures** ICMJE (submitted: November 8, 2008) | • Time to failure [ Designated as safety issue: No ]<br>• Disease-specific survival [ Designated as safety issue: No ]<br>• Freedom from biochemical recurrence (FFBR) [ Designated as safety issue: No ]<br>• Overall survival [ Designated as safety issue: No ]<br>• Incidence of GU and GI acute and late toxicity [ Designated as safety issue: Yes ]<br>• Statistical modeling of genomic biomarkers [ Designated as safety issue: No ] |

caDSR

# CDE Browser



Data Element Search

Refresh tree

- caDSR Contexts
  - BRIDG (BRIDG Collaboration)
  - caBIG (NCI cancer Biomedical Informatics G
  - caBIG CDE Data Standards (Shortcut)
  - caCORE (NCI Core Infrastructure)
  - CCR (NCI Center for Cancer Research)
  - CDISC (Clinical Data Interchange Standards
  - CIP (NCI Cancer Imaging Program)
  - CTEP (NCI Cancer Therapy Evaluation Progr
  - DCP (NCI Division of Cancer Prevention)
  - EDRN (NCI Early Research Detection Prograi
  - HITSP (Health Information Technology Stan
  - NCRI (National Cancer Research Institute, U
  - NHLBI (National Heart, Lung and Blood Insti
  - NICHD (National Institute of Child Health and
  - NIDCR (National Institute of Dental and Cran
  - NINDS (National Institute of Neurological Dis
  - PS&CC (NCI Population Sciences & Cancer
  - SPOREs (NCI Specialized Programs of Rese

## Search by Name

No Matches | Search preferences | Basic search

caDSR Contexts>>CTEP (NCI Cancer Therapy Evaluation Program)>>Protocol Forms>>RTOG-0415

- (•) Exact phrase
- ( ) All of the words
- ( ) At least one of the words

331773

Tip: To search for partial words or phrases use the * as a wildcard.

Note: Default settings exclude Test and Training Context views from the tree and certain 'non-released' Workflow and Registration statuses. Click the 'Search Preferences' link above to view or change the exclusion criteria. Search Preferences' will be reset to default settings when the 'New Search' button is clicked on the search results page or 'caDSR Context' in the Tree.

**Search in the following field(s)**

ALL
Long Name
Short Name
Preferred Question Text

Tip: Use Shift or Ctrl to select multiple fields.

## Search by Concept

| Concept Name | | Concept Code | |
|---|---|---|---|

## Search by Attributes

| | | | |
|---|---|---|---|
| Public ID | | Alternate Name | |
| Data Element Concept | Clear | Alternate Name Type(s) | ALL<br>3.1 VM Name<br>ABBREVIATION |
| Classification | Clear | Object Class | |
| Value Domain | Clear | Property | |
| Permissible Value | | | |

(•) Exact phrase ( ) All words ( ) At least one word

## Limit search results using filters

| Version | (•) Latest Version ( ) All Versions | Context Use | Owned By/Used By |
|---|---|---|---|

| | |
|---|---|
| | • At least 30 days since prior finasteride<br>• At least 90 days since prior dutasteride<br>• No concurrent neoadjuvant or adjuvant hormonal therapy<br>• Concurrent warfarin or other blood-thinning agents allowed |
| **Gender** | Male |
| **Ages** | 18 Years and older |
| **Accepts Healthy Volunteers** | No |
| **Contacts** ICMJE | *Contact information is only displayed when the study is recruiting subjects* |
| **Location Countries** ICMJE | United States, Canada |

## Administrative Information

| | |
|---|---|
| **NCT ID** ICMJE | NCT00331773 |
| **Other Study ID Numbers** ICMJE | CDR0000481119, RTOG-0415 |
| **Responsible Party** | Walter John Curran, Jr, Radiation Therapy Oncology Group |
| **Study Sponsor** ICMJE | Radiation Therapy Oncology Group |
| **Collaborators** ICMJE | National Cancer Institute (NCI) |
| **Investigators** ICMJE | Study Chair: W. Robert Lee, MD Duke University |
| **Information Provided By** | National Cancer Institute (NCI) |
| **Verification Date** | November 2009 |

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**

caDSR

# CDE Browser

CDE Cart | Home | FormBuilder | Help

Admin Tool | Curation Tool | NCI Metathesaurus | NCI Terminology Server | Sentinel Tool | UML Model Browser | What's new

Refresh tree

- caDSR Contexts
  - BRIDG (BRIDG Collaboration)
  - caBIG (NCI cancer Biomedical Informatics Grid)
  - caBIG CDE Data Standards (Shortcut)
  - caCORE (NCI Core Infrastructure)
  - CCR (NCI Center for Cancer Research)
  - CDISC (Clinical Data Interchange Standards Cons
  - CIP (NCI Cancer Imaging Program)
  - CTEP (NCI Cancer Therapy Evaluation Program)
    - Classifications
    - Protocol Forms
      - 8214
      - 8788
      - ACOSOG-Z1031
      - ACOSOG-Z1041
      - ACOSOG-Z1071
      - ACOSOG-Z1072
      - ACOSOG-Z4032
      - ACOSOG-Z4051
      - ACOSOG-Z5041
      - ACOSOG-Z6041
      - ACOSOG-Z6051
      - Adverse Events Mapping
      - AMC 044
      - AMC-038
      - AMC-040
      - AMC-042
      - AMC-045
      - AMC-046
      - AMC-047
      - AMC-048
      - AMC-050
      - AMC-051

Data Element Search

## Search for Data Elements

No Matches | Search preferences | Advanced search

caDSR Contexts>>CTEP (NCI Cancer Therapy Evaluation Program)>>Protocol Forms>>RTOG-0415

- (•) Exact phrase
- ( ) All of the words
- ( ) At least one of the words

[ ] Name

Tip: This is an exact match search. To search for partial words or phrases use the * as a wildcard.

Note: Default settings exclude Test and Training Context views from the tree and certain 'non-released' Workflow and Registration statuses. Click the 'Search Preferences' link above to view or change the exclusion criteria. Search Preferences' will be reset to default settings when the 'New Search' button is clicked on the search results page or 'caDSR Context' in the Tree.

Search | Clear | New Search

## Search Results

Results fewer than expected? Check Search Preferences

| Long Name | Preferred Question Text | Owned By | Used By Context | Registration | Workflow Status | Public ID | Version |
|---|---|---|---|---|---|---|---|
| No data elements matching the search criteria found. | | | | | | | |

caDSR

## Search Results

Search within results

Results fewer than expected? Check Search Preferences

[Download Data Elements to Prior Excel] [Download Data Elements to Excel] [Download Data Elements as XML]
[Download CDE Browser DTDs]

Sort order : (Default) Registration Status>>Workflow Status>>Long Name [Ascending]

Add to CDE Cart | Add to CDE compare list | Compare CDEs

1 - 100 of 107 Next 7

- RTOG 0825
- RTOG 0834
- RTOG 0848
- RTOG 0920
- RTOG 1010
- RTOG 1016
- RTOG P-0011
- RTOG P-0126
- RTOG-0320
- RTOG-0412
- RTOG-0415
  - RTOG-0415 AE: Adverse Event Evaluati
  - RTOG-0415 F1: Follow-up Form
  - RTOG-0415 I1: Initial Evaluation Form
  - RTOG-0415 T1: Radiotherapy Form
- RTOG-0421
- RTOG-0436
- RTOG-0521
- RTOG-0522
- RTOG-0525
- RTOG-1014
- RTOG0214
- RTOG0232
- S0023
- S0100
- S0124
- S0201
- S0205
- S0210
- S0221
- S0226
- S0227
- S0230
- S0303
- S0307

| Long Name | Preferred Question Text | Owned By | Used By Context | Registration Status | Workflow Status |
|---|---|---|---|---|---|
| Performance Status Assessment Eastern Cooperative Oncology Group Scale | Performance Status (ECOG) | CTEP | DCP,SPOREs,caBIG | Standard | RELEASED |
| Adverse Event Report Ind-3 | Has an Adverse Event Expedited Report been submitted? | CTEP | | Qualified | RELEASED |
| Assessment Method Specify | Other Specify | CTEP | CTEP,caBIG | Qualified | RELEASED |
| Assessment Method Type | Method of Evaluation | CTEP | DCP,NIDCR,caBIG | Qualified | RELEASED |
| Assessment Performed Date | Date of Assessment | CTEP | DCP,NIDCR | Qualified | RELEASED |
| Associated Form Submission Date | Due date of corresponding form | CTEP | | Qualified | RELEASED |
| Associated Form Submission Type | Type of corresponding form | CTEP | | Qualified | RELEASED |
| Baseline PSA Date | Date of Baseline PSA | CTEP | | Qualified | RELEASED |
| Biochemical Progression Present Ind-3 | Has the patient been diagnosed with biochemical recurrence since submission of the last follow-up form? | CTEP | caBIG | Qualified | RELEASED |
| Biopsy Date | Date of Biopsy | CTEP | CCR,DCP,PS&CC,caBIG | Qualified | RELEASED |
| Cancer Follow-Up Status Date | Date of Last Clinical Assessment | CTEP | caBIG | Qualified | RELEASED |
| Cancer Follow-up Status Ind-3 | Has the patient had a documented clinical assessment for this cancer? | CTEP | caBIG | Qualified | RELEASED |

## Data Element

Check All Clear All

| | 1 | 2 | 3 |
|---|---|---|---|
| **Public ID** | 330 | 323 | 1285 |
| **Long Name** | Common Toxicity Criteria Adverse Event Grade | Common Toxicity Criteria Adverse Event Term Type | CTC Adverse Event Attribution Scale |
| **Short Name** | CTC_AE_GD | CTC_AE_TRM_TP | CTC_AE_ATTR_SCALE |
| **Document Text** | CTC Adverse Event Grade | CTC Adverse Event Term | CTC AE Attribution Code |
| **Definition** | the numeric indicator that describes the severity of an adverse event as defined in CTCAE. | the medical description of the adverse event using NCI CTC terminology. | relation of the causality between the treatment modality and the specific adverse event. |
| **Owned by Context** | CTEP | CTEP | CTEP |
| **Used by Context** | caBIG | SPOREs , CCR , caBIG , DCP | CIP , caBIG , NINDS |
| **Origin** | | | |
| **Workflow Status** | RELEASED | RELEASED | RELEASED |
| **Registration Status** | Qualified | Qualified | Qualified |
| **Version** | 8.0 | 3.0 | 3.0 |

## Permissible Values

6 Permissible values

| Value | Value meaning | Description |
|---|---|---|
| 0 | No adverse event or within normal limits | NO ADVERSE EVENT OR WITHIN NORMAL LIMITS |
| 1 | MILD ADVERSE EVENT | An experience that is usually transient, and requires no special treatment or intervention. The event does not generally interfere with usual daily activities. Includes transient laboratory test alterations. |
| 2 | MODERATE ADVERSE EVENT | An experience that is alleviated with simple therapeutic treatments. The event impacts usual daily activities. Includes laboratory test alterations indicating injury, but without long-term risk. |
| 3 | SEVERE ADVERSE EVENT | Severe adverse event is an experience that requires therapeutic intervention. The event interrupts usual daily activities. If hospitalization is required for treatment it becomes a serious adverse event. |
| 4 | LIFE-THREATENING OR DISABLING | LIFE-THREATENING OR DISABLING ADVERSE |

1059 Permissible values

| Value | Value meaning | Description |
|---|---|---|
| Acidosis (metabolic or respiratory) | Acidosis NOS | Acidosis NOS |
| Acute vascular leak syndrome | Capillary leak syndrome | Capillary leak syndrome |
| Adrenal insufficiency | Adrenal insufficiency | Adrenal insufficiency |
| Adult respiratory distress syndrome (ARDS) | Adult respiratory distress syndrome | Adult respiratory distress syndrome |
| Albumin, serum-low (hypoalbuminemia) | Blood albumin decreased | Blood albumin decreased |
| Alcohol intolerance syndrome (antabuse-like syndrome) | Alcohol intolerance syndrome (antabuse-like syndrome) | Alcohol intolerance syndrome (antabuse-like syndrome) |
| Alkaline phosphatase | Blood alkaline phosphatase NOS increased | Blood alkaline phosphatase NOS increased |
| Alkalosis (metabolic or respiratory) | Alkalosis NOS | Alkalosis NOS |
| Allergic reaction/hypersensitivity (including drug fever) | Hypersensitivity NOS | Hypersensitivity NOS |
| Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip) | Rhinitis allergic NOS | Rhinitis allergic NOS |
| Allergy/Immunology-Other (Specify) | ALLERGY/IMMUNOLOGY OTHER | an allergy/immunology related item that is not otherwise specified - description required |
| ALT, SGPT (serum glutamic pyruvic transaminase) | Alanine aminotransferase increased | Alanine aminotransferase increased |
| Amylase | Blood amylase increased | Blood amylase increased |
| Anorexia | Anorexia | Loss of appetite. |
| Apnea | Apnoea | Apnoea |

5 Permissible values

| Value | Value meaning | Description |
|---|---|---|
| Definite | DEFINITE | No Value Exists |
| Possible | POSSIBLE | POSSIBLE |
| Probable | PROBABLE | PROBABLE |
| Unlikely | UNLIKELY | UNLIKELY |
| Unrelated | UNRELATED | UNRELATED |

PAGE 5 OF THE QUESTIONNAIRE

A22. Children in our class fight a lot

Yes [1] No [2]

A23. A few children in my class want to be first all of the time

Yes [1] No [2]

A24. Most of the pupils in my class know how to do their work

Yes [1] No [2]

**ccd200 A21: The class is fun**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | 1 Yes | 3270 | 39.9 | 40.2 | 40.2 |
| | 2 Sometimes | 4552 | 55.5 | 55.9 | 96.1 |
| | 3 No | 321 | 3.9 | 3.9 | 100.0 |
| | Total | 8143 | 99.4 | 100.0 | |
| Missing | -1 No response | 53 | .6 | | |
| Total | | 8196 | 100.0 | | |

**ccd205 A22: Children in child's class fight a lot**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | 1 Yes | 1658 | 20.2 | 20.4 | 20.4 |
| | 2 No | 6426 | 78.4 | 79.1 | 99.6 |
| | 3 Sometimes | 36 | .4 | .4 | 100.0 |
| | Total | 8120 | 99.1 | 100.0 | |
| Missing | -1 No response | 76 | .9 | | |
| Total | | 8196 | 100.0 | | |

**ccd210 A23: A few children in child's class want to be first all the time**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | 1 Yes | 5446 | 66.4 | 67.3 | 67.3 |
| | 2 No | 2634 | 32.1 | 32.5 | 99.8 |
| | 3 Sometimes | 17 | .2 | .2 | 100.0 |
| | Total | 8097 | 98.8 | 100.0 | |
| Missing | -9 Don't know | 1 | .0 | | |
| | -1 No response | 98 | 1.2 | | |
| | Total | 99 | 1.2 | | |
| Total | | 8196 | 100.0 | | |

**ccd215 A24: Most of the pupils in child's class know how to do their work**

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---|---|---|---|---|---|
| Valid | 1 Yes | 7421 | 90.5 | 91.4 | 91.4 |
| | 2 No | 687 | 8.4 | 8.5 | 99.9 |
| | 3 Sometimes | 11 | .1 | .1 | 100.0 |
| | Total | 8119 | 99.1 | 100.0 | |
| Missing | -1 No response | 77 | .9 | | |
| Total | | 8196 | 100.0 | | |

# Model: KA SPSS Data Dictionary

as XSD as XML

## Administered Item - Preferred Name: KA SPSS Data Dictionary

| | |
|---|---|
| Administered Item Identifier | GB-OUCL-473688D8-1.0 |
| Registration Status *explain* | Application |
| Definition | test |
| Registered By | Steve Harris (Research Fellow)<br>Oxford Comlab |

## Model Specific Attributes

| | |
|---|---|
| Mime-type | text/xml |
| Model Type | SPSS Metadata File |
| Model Content | Download |

## Annotations

| identifier | names | related to | how |
|---|---|---|---|
| GB-OUCL-5DBCC03E-1.0 | **Questionnaire version (Form type)**<br>ka001 | GB-OUCL-AD1B9D47-1.0 | sameAs |
| GB-OUCL-468D233C-1.0 | **Reaction at birth**<br>ka010 | GB-OUCL-E5C6AD44-1.0 | sameAs |
| GB-OUCL-1E2D0AEA-1.0 | **Time until put to breast**<br>ka011 | GB-OUCL-0126D16D-1.0 | sameAs |
| GB-OUCL-1143400B-1.0 | **Time next to mum in 1st 2 days**<br>ka012 | GB-OUCL-0908C607-1.0 | sameAs |
| GB-OUCL-D1C68AD5-1.0 | **Time next to mum in 1st 2 nights**<br>ka013 | GB-OUCL-97D01A7B-1.0 | sameAs |
| GB-OUCL-3B4C55B6-1.0 | **Time next to mum in 1st 2 nights (adjusted)**<br>ka013a | GB-OUCL-03B88B17-1.0 | sameAs |
| GB-OUCL-0D5AB2E1-1.0 | **Admission to SCBU etc**<br>ka014 | GB-OUCL-13BAAA42-1.0 | sameAs |
| GB-OUCL-92534E0B-1.0 | **Readmitted to hospital**<br>ka020 | GB-OUCL-1C06DB4D-1.0 | sameAs |
| GB-OUCL-E8884D70-1.0 | **Duration of stay**<br>ka021 | GB-OUCL-241A9B79-1.0 | sameAs |

MRC Data Support Service

welcome: guest

metadata registry

browse search discover understand login

# Data Element: Baby breast fed

as XML

**Administered Item - Preferred Name: Baby breast fed**

| | |
|---|---|
| Administered Item Identifier | GB-OUCL-91690359-1.0 |
| Registration Status *explain* | Application |
| Definition | (undefined) |
| Registered By | Steve Harris (Research Fellow)<br>Oxford Comlab |

## Value Domain Attributes

| | |
|---|---|
| Value domain record | Baby breast fed |
| Conceptual Domain | Baby breast fed |
| Datatype | xs:string (XMLSchema) |
| Unit of Measure | |
| Format | not specified |
| Maximum Character Quantity | not specified |
| Representation Class | |

## Valid Values

Valid Values

| value | meaning | uri |
|---|---|---|
| -1 | Missing | |
| 1 | Always | |
| 2 | Often | |
| 3 | Sometimes | |
| 4 | Never | |

## Field Names

Field Names

| field name | preferred |
|---|---|
| ka094 | true |

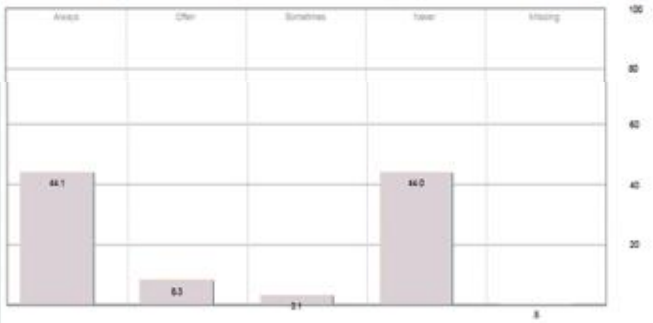
## Model Reference

| | |
|---|---|
| Expresses data element concept (full record) | Baby breast fed |
| Object class | default object class |
| Property | default property |
| Precision | 0 |
| Example | not specified |
| Typed by Representation Class | not-specified |
| Representation Class Qualifier | unqualified |
| Related data elements | |

## Reference Documents

Reference Documents

| id | language | title | description |
|---|---|---|---|
| C5DD288C6 | eng | ka094 Baby breast fed | Frequency plots associated with ALSPAC variables |



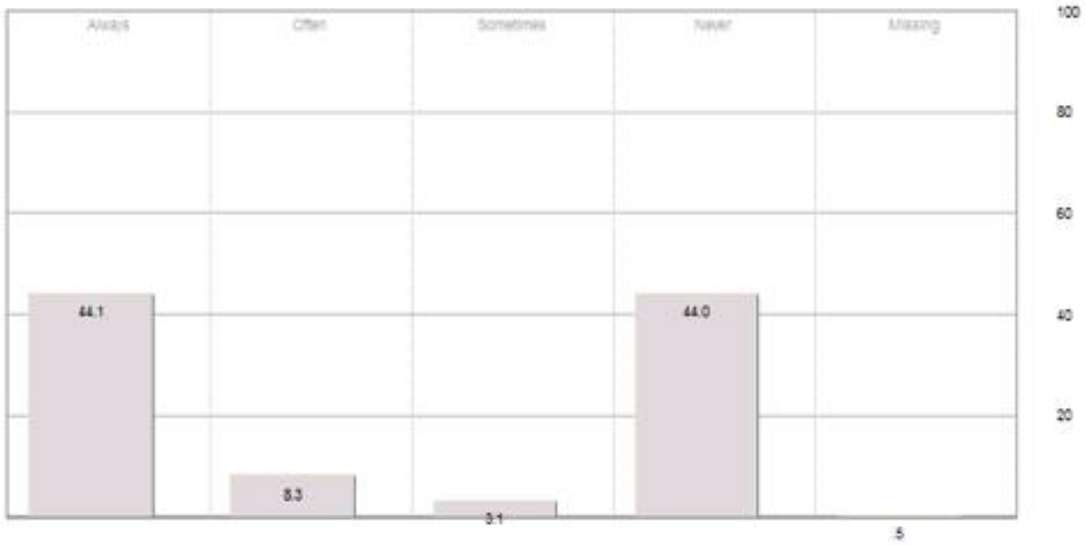

## Naming

| | |
|---|---|
| Representation Class Qualifier | unqualified |
| Related data elements | |

## Reference Documents

Reference Documents

| id | language | title | description |
|---|---|---|---|
| C5DD288C6 | eng | ka094 Baby breast fed | Frequency plots associated with ALSPAC variables |




## Naming

Naming

| context | language | name | preferred |
|---|---|---|---|
| Avon Longitudinal Study of Parents and Children | GB-eng | Baby breast fed | true |
| Avon Longitudinal Study of Parents and Children | GB-eng | ka094 | false |

## Administration

| | |
|---|---|
| Administrative Status *explain* | noPendingChanges |
| Administered By | Steve Harris<br>Research Fellow |
| Created On | not-specified |
| Effective From | not-specified |



23

# Variable: 'Can carer understand child' Speech Q 25 mth

supersede | edit | as XSD | as XML

**Administered Item - Preferred Name: 'Can carer understand child' Speech Q 25 mth**

| | |
|---|---|
| Administered Item Identifier | GB-OUCL-7D36B7A8443C4E7E91E418677117EC83-1 add to cart |
| Registration Status *explain* | Recorded |
| Definition | not-specified |
| Registered By | Dr. Steve Harris (Researcher, IDH)<br>Oxford Comlab |

## Value Domain Attributes

| | |
|---|---|
| Value domain record | Value domain for cf414 |
| Conceptual Domain | Conceptual domain for cf414 |
| Datatype | xs:string (XMLSchema) |
| Unit of Measure | |
| Format | not specified |
| Maximum Character Quantity | not specified |

## Valid Values

Valid Values

| value | meaning |
|---|---|
| -1 | Missing |
| -2 | Did not attend |
| 1 | most of time |
| 2 | sometimes |
| 3 | rarely |
| 4 | doesnt talk at all |

## Field Names

Field Names

| field name | preferred |
|---|---|
| cf414 | true |

## Usage

Related data elements

Children in Focus part of dataset

'Takes turns talking' Speech Q 25 mth precedes this data element in dataset

'How often follows instructions' Speech Q 25 mth precedes this data element in dataset

'Points to body parts' Speech Q 25 mth precedes this data element in a dataset

'How describe childs talking' Speech Q 25 mth follows this data element in a dataset

'Hoarse/husky voice' Speech Q 25 mth follows this data element in a dataset

'Stuck/repeat words' Speech Q 25 mth follows this data element in a dataset

## Classification

Classification

| term |
|---|
| 25 months |
| Children in Focus dictionary |

# Data Element by Classifier

Search within classification

(reset form)

Schemes

ALSPAC by age

Classification

broader terms

Alspac by child age

selected term

134 months

related terms

8 wks gest
12 wks gest
18 wks gest
32 wks gest
4 weeks
8 weeks
4 months
6 months
8 months
12 months
15 months
18 months
21 months
24 months
25 months
30 months
31 months
33 months
37 months
38 months
42 months

| Origin | Names | Definitions | Values |
|---|---|---|---|
| ALSPAC | A1a: Child's school is a place where they really like to go each day<br>ccj100<br>add to cart<br>A1a: Child's school is a place where they really like to go each day | (undefined) | *data type:* xs:string<br>*units:*<br>*enumerations:*<br>-1 No response-10 Not completed-11 Triplet / quadruplet1 Agree2 Mostly agree3 Mostly disagree4 Disagree99 DK |
| ALSPAC | A1a: Frequency respondent felt things spinning/moving around, lasting less than 2 minutes during past 12 months<br>r1000<br>add to cart<br>A1a: Frequency respondent felt things spinning/moving around, lasting less than 2 minutes during past 12 months | (undefined) | *data type:* xs:string<br>*units:*<br>*enumerations:*<br>-1 No response-10 Not completed-11 Triplet / quadruplet0 Other text answer1 > than once a week2 > than once a month3 4-12 times4 1-3 times5 Not at all9 DK |
| ALSPAC | A1a: Frequency respondent has felt things spinning/moving for less than 2 mins in past 12 months<br>pp1000<br>add to cart<br>A1a: Frequency respondent has felt things spinning/moving for less than 2 mins in past 12 months | (undefined) | *data type:* xs:string<br>*units:*<br>*enumerations:*<br>-1 No response-10 Not completed-11 Triplet / quadruplet1 > Once a week2 > Once a month3 4-12 times4 1-3 times5 Not at all |
| ALSPAC | A1b: Child's school is a place where their teacher is fair to them<br>ccj101<br>add to cart<br>A1b: Child's school is a place where their teacher is fair to them | (undefined) | *data type:* xs:string<br>*units:*<br>*enumerations:*<br>-1 No response-10 Not completed-11 Triplet / quadruplet1 Agree2 Mostly agree3 Mostly disagree4 Disagree99 DK |
| ALSPAC | A1b: Frequency respondent felt things spinning/moving around, lasting up to 20 minutes during past 12 months<br>r1001<br>add to cart<br>A1b: Frequency respondent felt things spinning/moving around, lasting up to 20 minutes during past 12 months | (undefined) | *data type:* xs:string<br>*units:*<br>*enumerations:*<br>-1 No response-10 Not completed-11 Triplet / quadruplet0 Other text answer1 > than once a week2 > than once a month3 4-12 times4 1-3 times5 Not at all9 DK |

# Model Listing

a b c d e f g h i j k l m n o p q r s t u v w x y z

| Names | Definition |
|---|---|
| F File | DATA COLLECTED FROM THE QUESTIONNAIRE 'Looking After the Baby' at 8 months |
| Focus 10 + | The aim of 'Children in Focus' was to examine the children in a way that cannot be done using questionnaires to their parents. The sample provides both a validation for certain aspects of the self-completion questionnaires and an answer to some important questions. These are related, for example, to the ways in which childhood diet, growth, anaemia, otitis media with effusion, visual defects, parenting skills and early cognition are related to the development of intellectual competence, speech and language as well as motor development of the child |
| Focus 11 + | The aim of 'Children in Focus' was to examine the children in a way that cannot be done using questionnaires to their parents. The sample provides both a validation for certain aspects of the self-completion questionnaires and an answer to some important questions. These are related, for example, to the ways in which childhood diet, growth, anaemia, otitis media with effusion, visual defects, parenting skills and early cognition are related to the development of intellectual competence, speech and language as well as motor development of the child |
| Focus @ 7 | The aim of 'Children in Focus' was to examine the children in a way that cannot be done using questionnaires to their parents. The sample provides both a validation for certain aspects of the self-completion questionnaires and an answer to some important questions. These are related, for example, to the ways in which childhood diet, growth, anaemia, otitis media with effusion, visual defects, parenting skills and early cognition are related to the development of intellectual competence, speech and language as well as motor development of the child |
| Focus @ 9 | The aim of 'Children in Focus' was to examine the children in a way that cannot be done using questionnaires to their parents. The sample provides both a validation for certain aspects of the self-completion questionnaires and an answer to some important questions. These are related, for example, to the ways in which childhood diet, growth, anaemia, otitis media with effusion, visual defects, parenting skills and early cognition are related to the development of intellectual competence, speech and language as well as motor development of the child |

start prev 1 to 5 of 6 next last

Whitehall Timeline

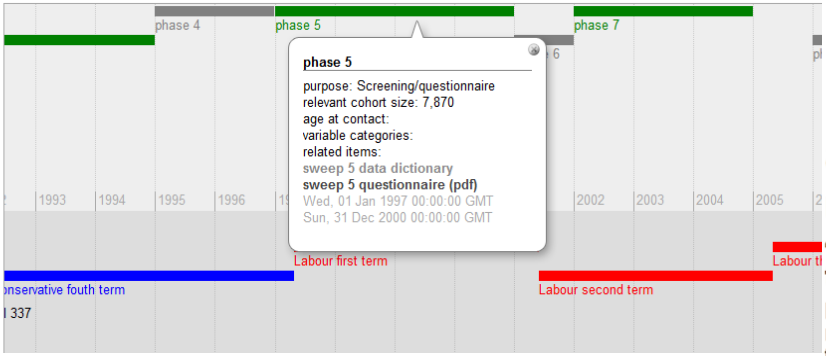
https://localhost:8443/exist/mdr/timeline/timeline-new.xql

PTCRI | Metadata | Admin | Modelling | Clinical Trials | XML | selenium | MRC DSS | Personal | eGov | IST/40 | RDFa Highligh

MRC Data Support Service

search browse discover understand login

## Whitehall Timeline




MRC Data Support Service

welcome: guest

search browse discover understand login

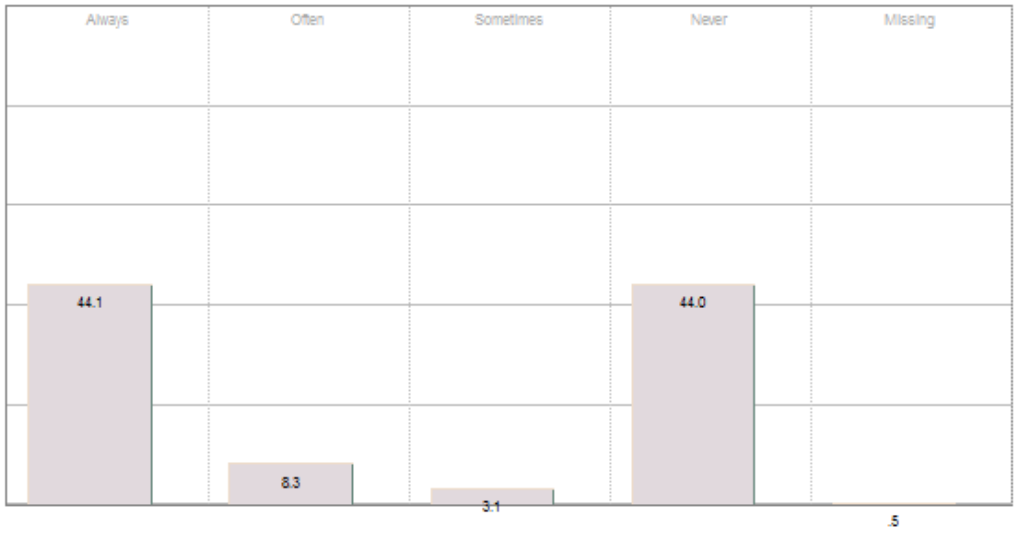
## Tag Cloud View

last hospital months 12 hrt year sm admission 1998 october patient name month symptoms 1950 study first age health reason day 4 doctor 1999 whether used much years names preparations life taken problem during 2nd stopped 1st child occasion time weeks period 10 prescribed recently old periods children cohort test work up hysterectomy everyday 3rd reasons preparation bothered many card chest breast 3 give mother urine pressure medicine being illness go days felt town pain blood s partner importance important menstrual admitted order 1-3 mammogram ranking started charge recent more 4th condition oopherectomy household ward private treated diagnosis case



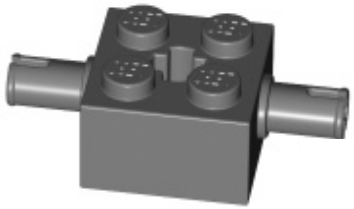
## Reference Documents

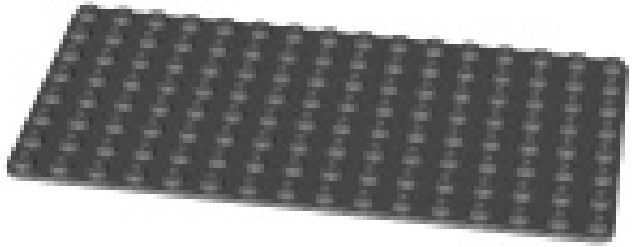
| id | language | title |
|---|---|---|
| C5DD288C6 | eng | ka094 Baby breas |

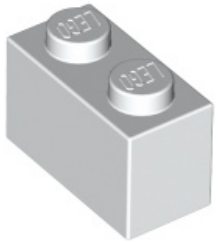


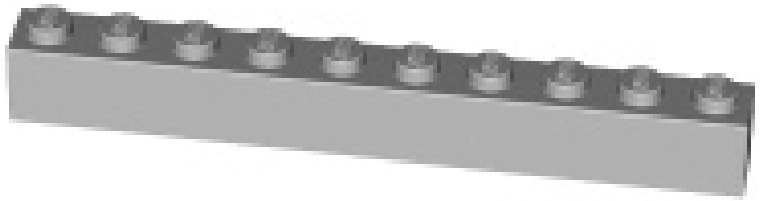

cancergrid W3C XHTML + RDFa W3C CSS eXist

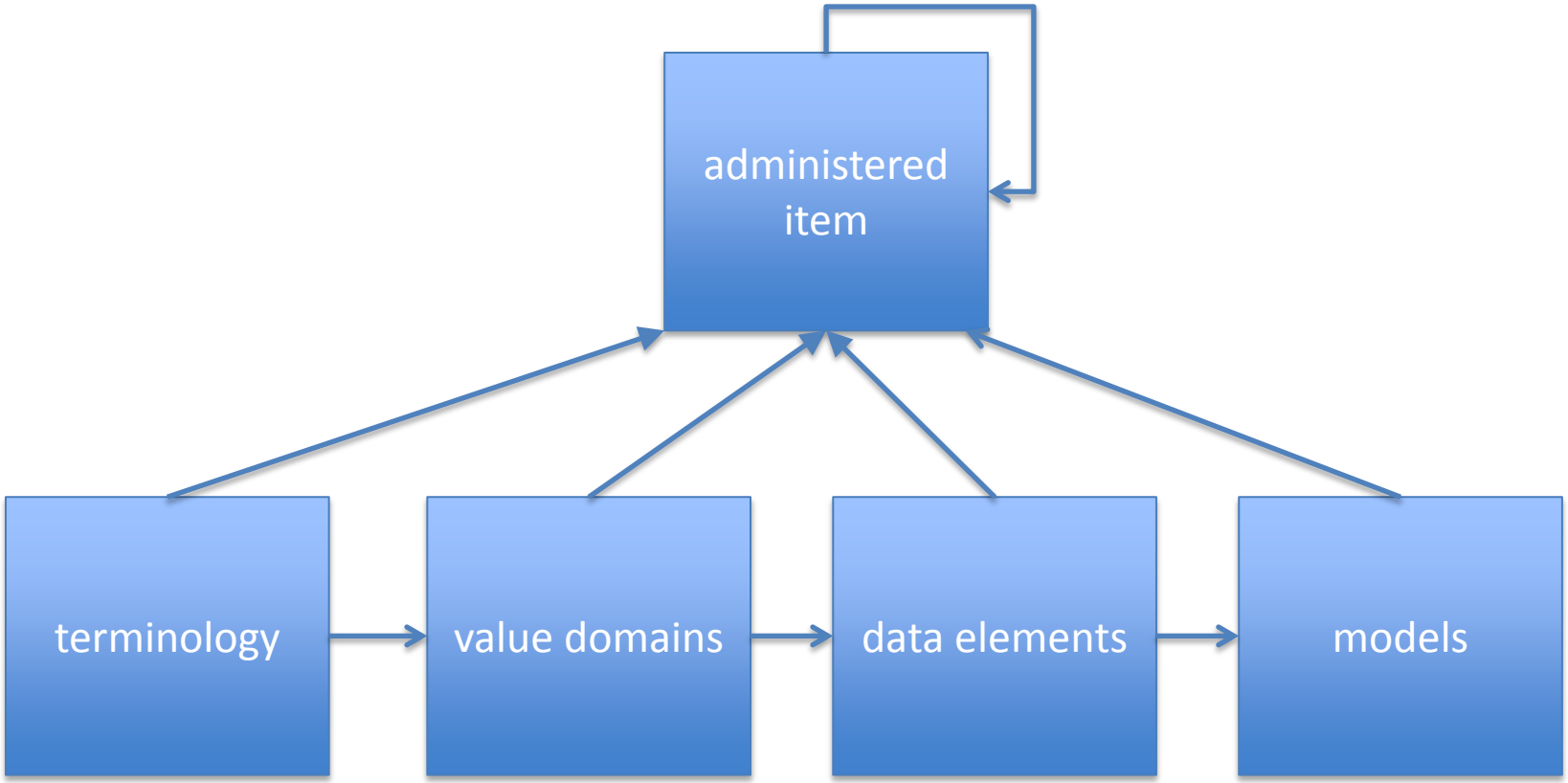
# SEMANTIC SOFTWARE GENERATION






administered item
terminology
value domains
data elements
models

# Data Element: CASP total score (CASP-19) (S7-d)

as XSD as XML

### Administered Item - Preferred Name: CASP total score (CASP-19) (S7-d)

| | |
|---|---|
| Administered Item Identifier | GB-OUCL-856DD873-1 |
| Registration Status *explain* | Recorded |
| Definition | not-specified |
| Registered By | Dr. Steve Harris (Researcher, IDH)<br>Oxford Comlab |

## Value Domain Attributes

| | |
|---|---|
| Value domain record | **Value Domain for CASP total score (CASP-19) (S7-d)** |
| Conceptual Domain | **Conceptual Domain for CASP total score (CASP-19) (S7-d)** |
| Datatype | **xs:double (XMLSchema)** |
| Unit of Measure | |
| Format | not specified |
| Maximum Character Quantity | not specified |
| Representation Class | |

## Field Names

| Field Names | field name | preferred |
|---|---|---|
| | MCASPTOT | true |

## Model Reference

| | |
|---|---|
| Expresses data element concept (full record) | **Data Element Concept for CASP total score (CASP-19) (S7-d)** |
| Object class | **default object class** |
| Property | **default property** |
| Precision | 0 |
| Example | not specified |
| Typed by Representation Class | not-specified |

# Data Element: CASP total score (CASP-19) (S7-d)

as XSD as XML

### Administered Item - Preferred Name: CASP total score (CASP-19) (S7-d)

| | |
|---|---|
| Administered Item Identifier | GB-OUCL-856DD873-1 |
| Registration Status *explain* | Recorded |
| Definition | not-specified |
| Registered By | Dr. Steve Harris (Researcher, IDH)<br>Oxford Comlab |

## Value Domain Attributes

| | |
|---|---|
| Value domain record | **Value Domain for CASP total score (CASP-19) (S7-d)** |
| Conceptual Domain | **Conceptual Domain for CASP total score (CASP-19) (S7-d)** |
| Datatype | **xs:double (XMLSchema)** |
| Unit of Measure | |
| Format | not specified |
| Maximum Character Quantity | not specified |
| Representation Class | |

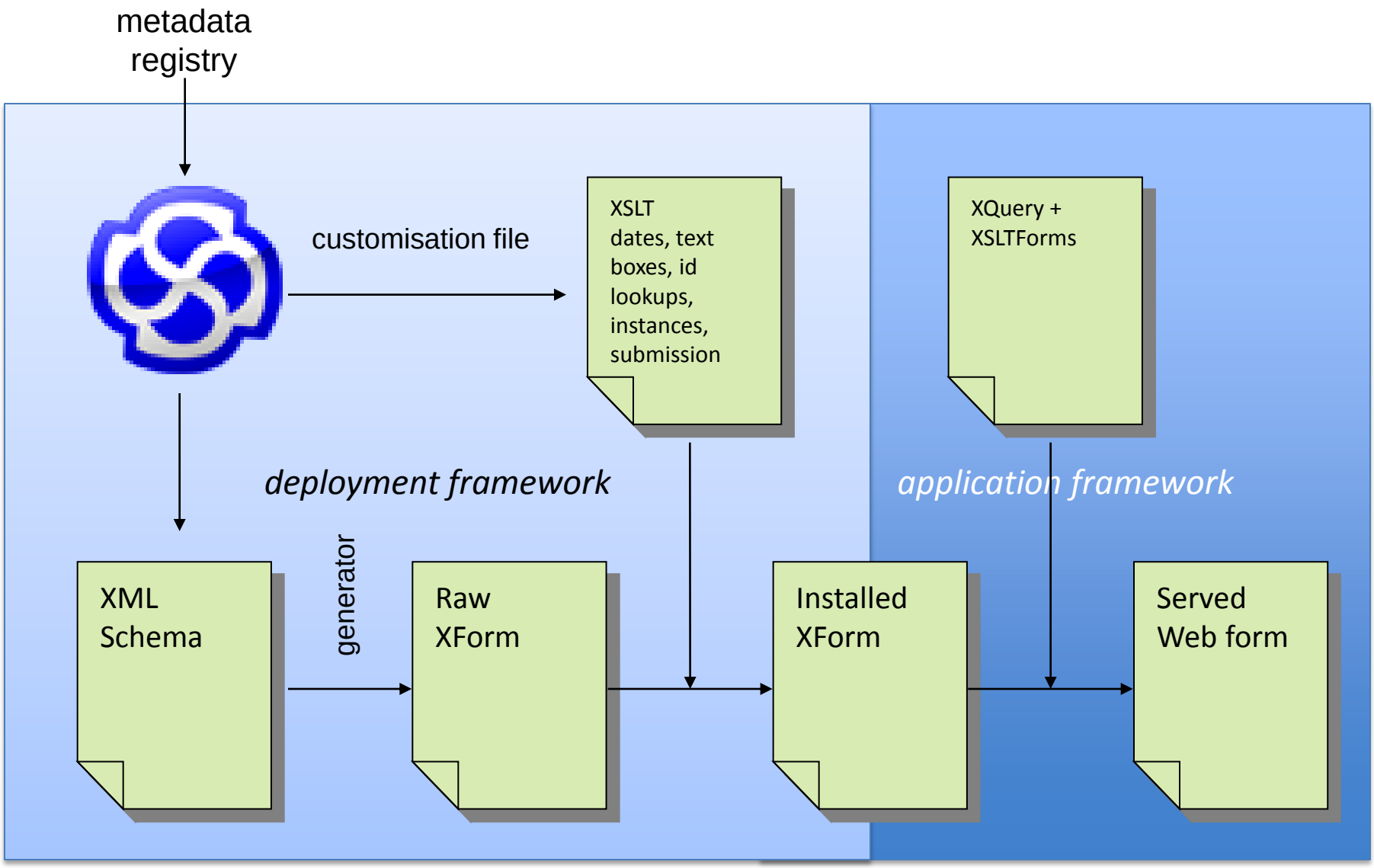
## Field Names

| Field Names | field name | preferred |
|---|---|---|
| | MCASPTOT | true |

## Model Reference

| | |
|---|---|
| Expresses data element concept (full record) | **Data Element Concept for CASP total score (CASP-19) (S7-d)** |
| Object class | **default object class** |
| Property | **default property** |
| Precision | 0 |
| Example | not specified |
| Typed by Representation Class | not-specified |

```
- <xs:schema>
  + <xs:annotation></xs:annotation>
    <xs:element name="name_of_your_element" ref="MCASPTOT"/>
  - <xs:element name="MCASPTOT" type="GB-OUCL-4EA1E0CD-1" sawsdl:modelReference="GB-OUCL-856DD873-1">
    + <xs:annotation></xs:annotation>
    </xs:element>
  - <xs:simpleType name="GB-OUCL-4EA1E0CD-1" sawsdl:modelReference="GB-OUCL-4EA1E0CD-1">
      <xs:extension base="xs:double"/>
    - <xs:annotation>
      - <xs:documentation>
        - <cgMDR:Value_Domain item_registration_authority_identifier="GB-OUCL" data_identifier="4EA1E0CD" version="1">
          - <cgMDR:administered_item_administration_record>
              <cgMDR:registration_status>Recorded</cgMDR:registration_status>
              <cgMDR:administrative_status>noPendingChanges</cgMDR:administrative_status>
              <cgMDR:creation_date>2010-09-22</cgMDR:creation_date>
              <cgMDR:effective_date>2010-09-22</cgMDR:effective_date>
              <cgMDR:last_change_date>2010-09-22</cgMDR:last_change_date>
              <cgMDR:explanatory_comment>Created by the SAS Importer</cgMDR:explanatory_comment>
              <cgMDR:unresolved_issue/>
              <cgMDR:origin>GB-OUCL-230001-1</cgMDR:origin>
            </cgMDR:administered_item_administration_record>
            <cgMDR:administered_by>GB-OUCL-200002-1</cgMDR:administered_by>
            <cgMDR:registered_by>GB-OUCL-100009-1</cgMDR:registered_by>
            <cgMDR:submitted_by>GB-OUCL-230002-1</cgMDR:submitted_by>
            <cgMDR:described_by/>
          - <cgMDR:having>
              <cgMDR:context_identifier>GB-OUCL-CC93897D9-1</cgMDR:context_identifier>
            - <cgMDR:containing>
              - <cgMDR:language_section_language_identifier>
                  <cgMDR:country_identifier>GB</cgMDR:country_identifier>
                  <cgMDR:language_identifier>eng</cgMDR:language_identifier>
```


metadata registry
customisation file
XSLT dates, text boxes, id lookups, instances, submission
XQuery + XSLTForms
deployment framework
application framework
XML Schema
generator
Raw XForm
Installed XForm
Served Web form

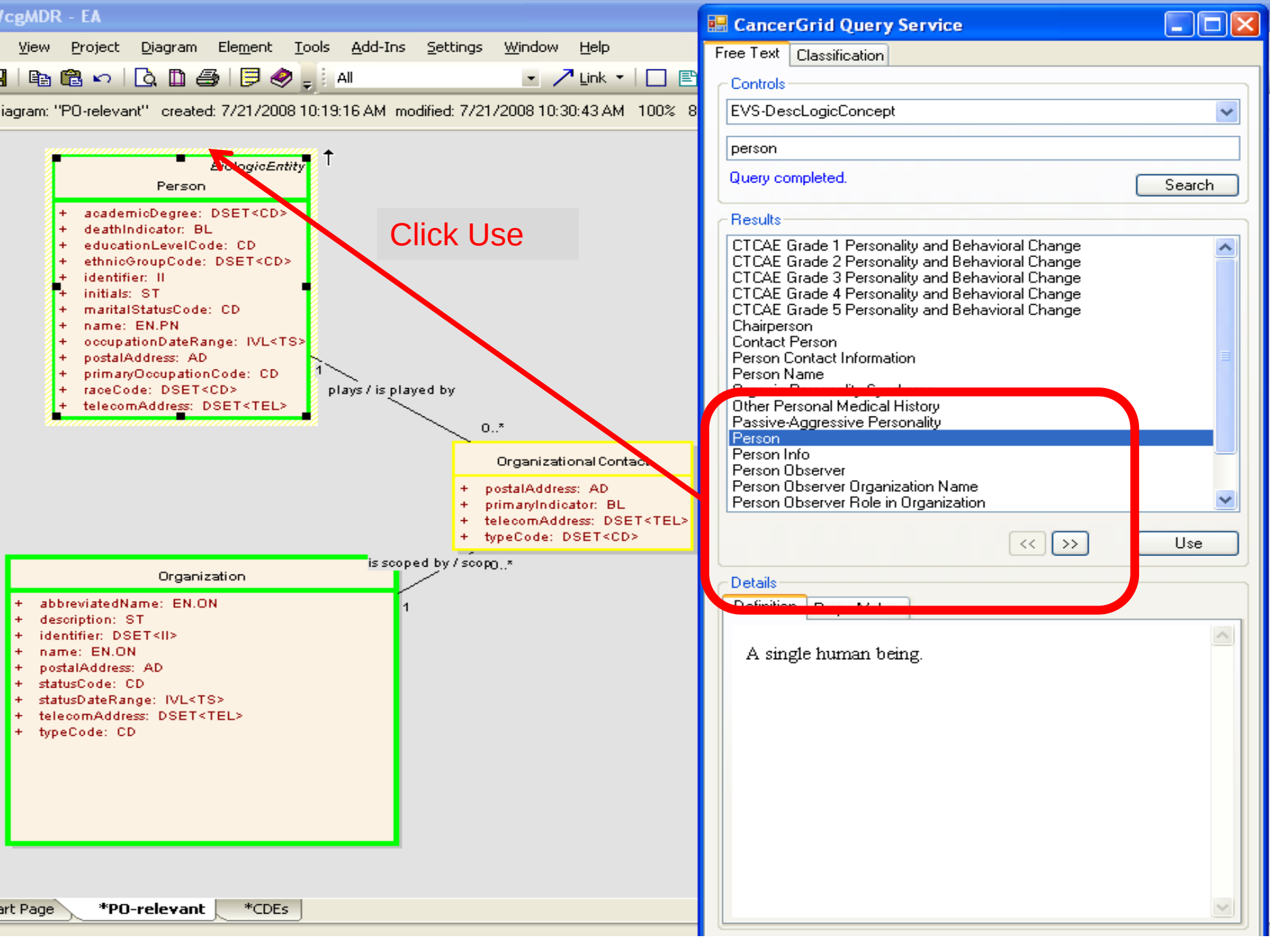
```
<xforms:input
    ref="//cgMDR:change_description">
        <xforms:label>Change Description</xforms:label>
</xforms:input>


<xsl:template match=
"xforms:input[ends-with(./@ref,'cgMDR:change_description')]">
      <xforms:textarea
         ref="//cgMDR:change_description">
         <xforms:label>Change Description </xforms:label>
      </xforms:textarea>
</xsl:template>



<xforms:textarea
    ref="//cgMDR:change_description">
        <xforms:label>Change Description</xforms:label>
</xforms:textarea>
```

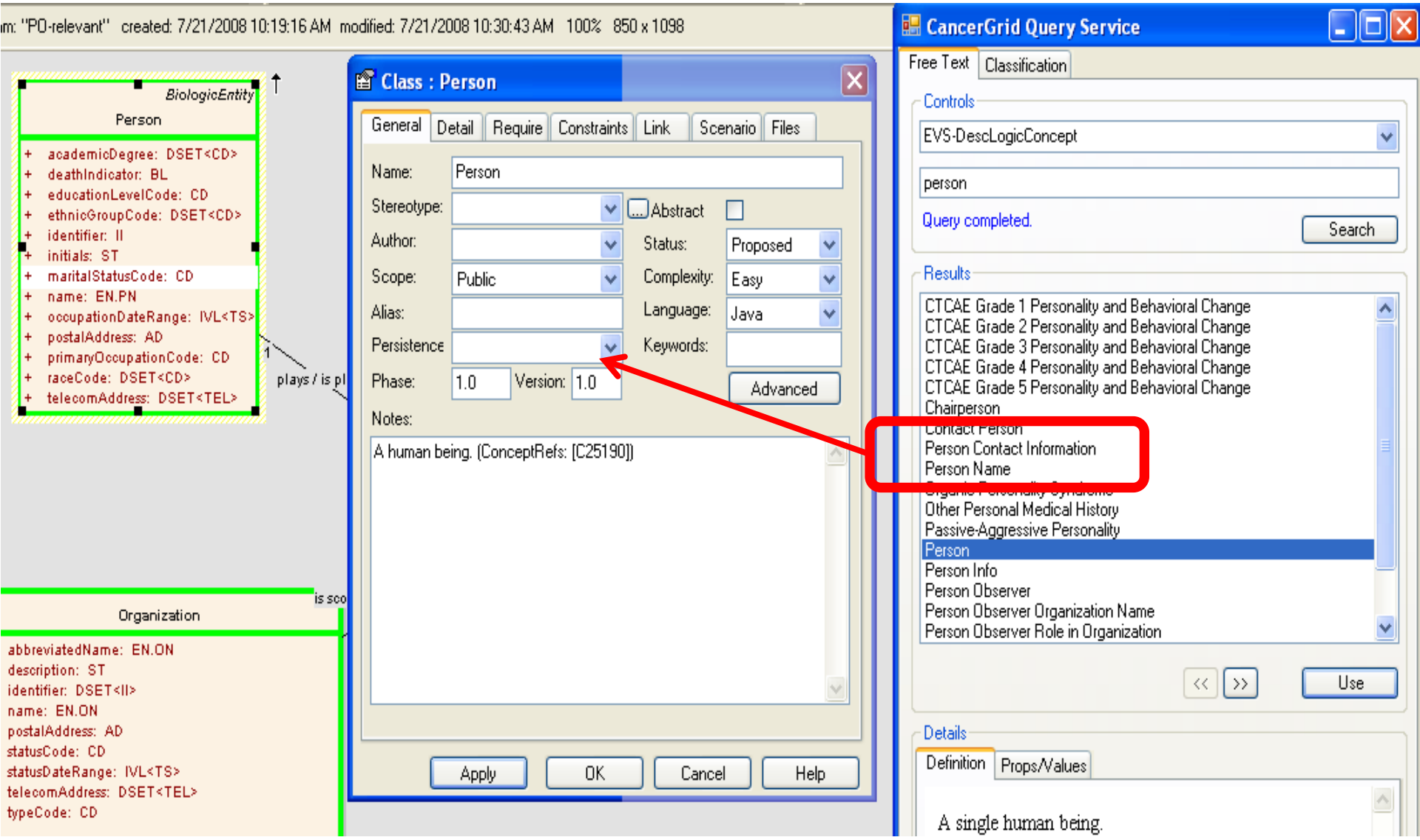
# sawsdl + cgMDR

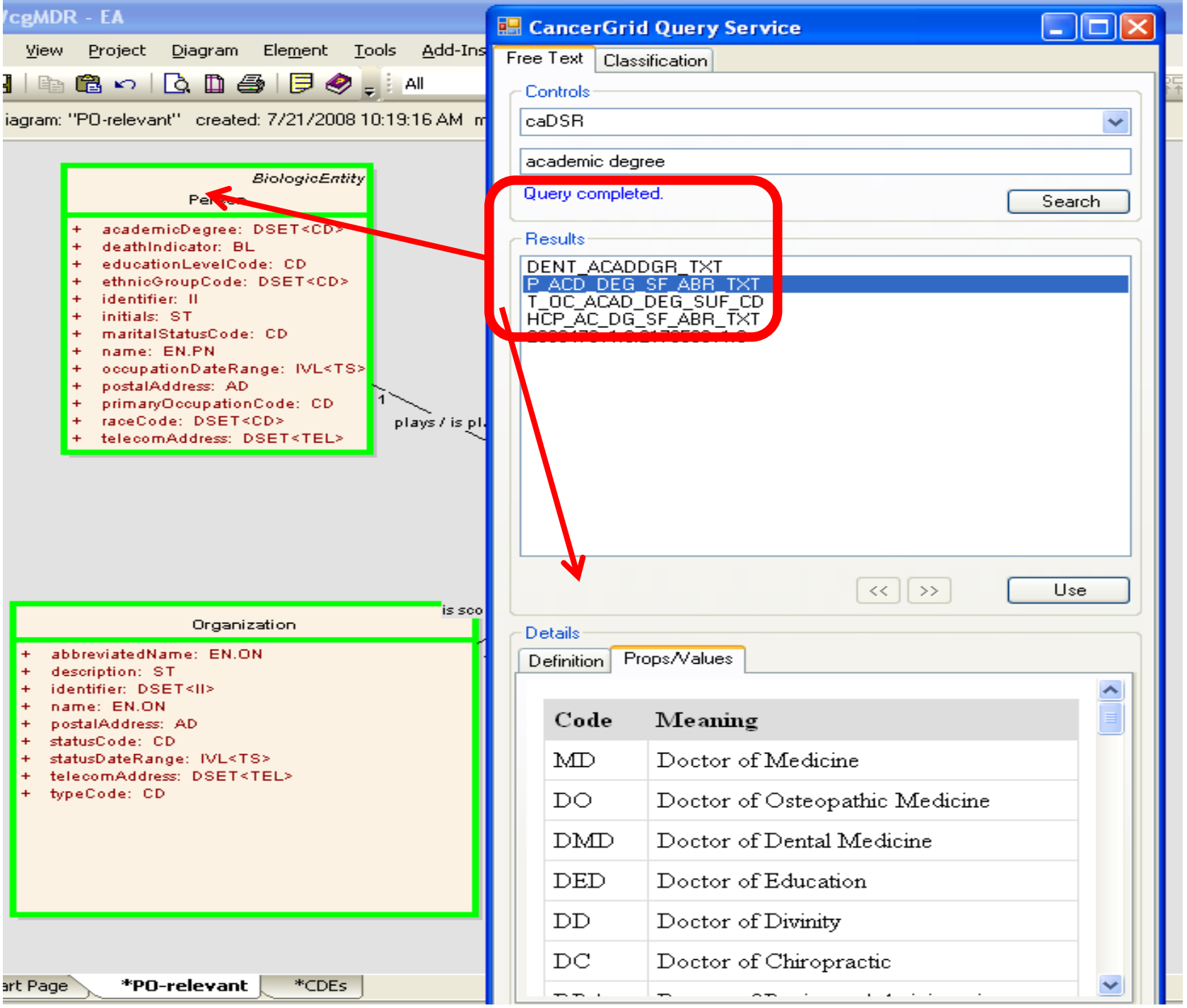
```
<?xml version="1.0" encoding="UTF-8"?>
<cg:trialProtocol xmlns:cg="http://www.cancergrid.org/protocol"

    xmlns:sawsdl="http://www.w3.org/ns/sawsdl"
…
<cg:name>Zubrod performance status score</cg:name>
<cg:cdeDataType>
 <xs:simpleType name="enumZubrodStatus"

   sawsdl:modelReference
      ="2.16.840.1.113883.3.26.2:2003315:42">

   <xs:restriction base="xs:string">
   <xs:enumeration value="0"/>
   <xs:enumeration value="1"/>
   <xs:enumeration value="2"/>
   <xs:enumeration value="3"/>
   <xs:enumeration value="4"/>
  </xs:restriction>
 </xs:simpleType>
</cg:cdeDataType>
…
```

tooling for the semantic framework

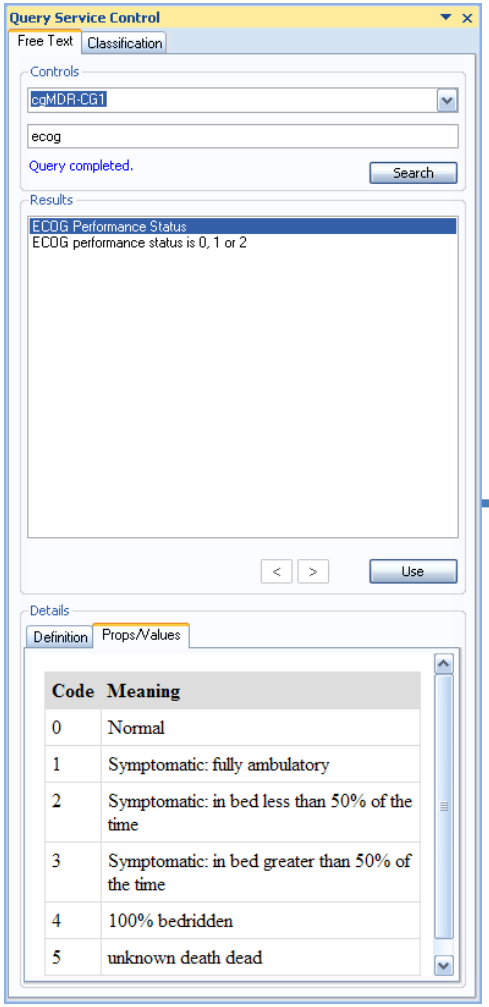
# SEMANTICS IN MODELS

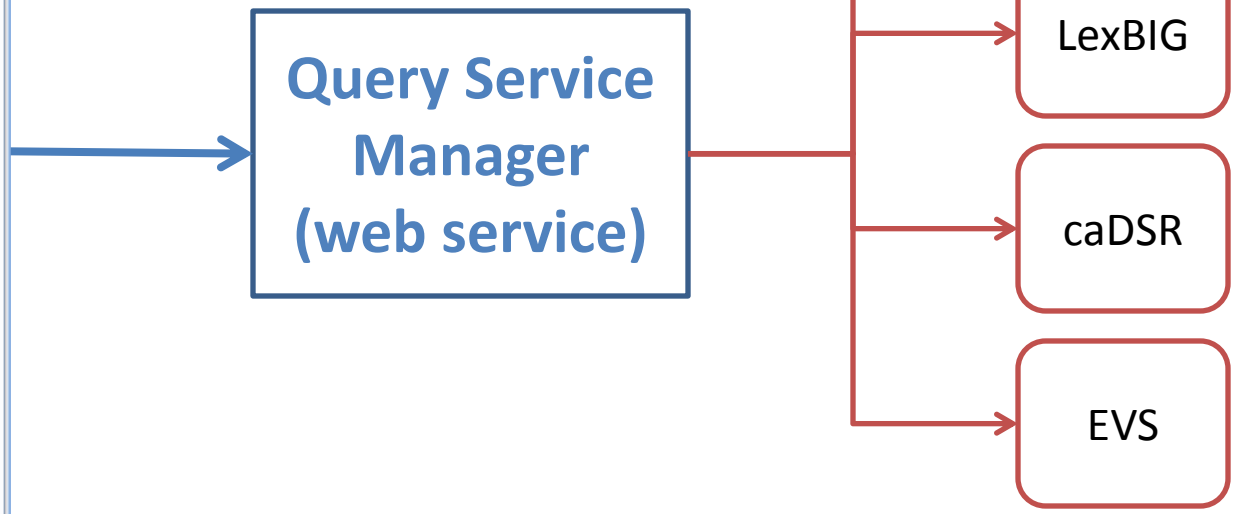

VcgMDR - EA
View Project Diagram Element Tools Add-Ins Settings Window Help
All
Link
iagram: "PO-relevant" created: 7/21/2008 10:19:16 AM modified: 7/21/2008 10:30:43 AM 100%
EVSlogicEntity
Person
+ academicDegree: DSET<CD>
+ deathIndicator: BL
+ educationLevelCode: CD
+ ethnicGroupCode: DSET<CD>
+ identifier: II
+ initials: ST
+ maritalStatusCode: CD
+ name: EN.PN
+ occupationDateRange: IVL<TS>
+ postalAddress: AD
+ primaryOccupationCode: CD
+ raceCode: DSET<CD>
+ telecomAddress: DSET<TEL>
Click Use
1
plays / is played by
0..*
Organizational Contact
+ postalAddress: AD
+ primaryIndicator: BL
+ telecomAddress: DSET<TEL>
+ typeCode: DSET<CD>
is scoped by / scop
0..*
1
Organization
+ abbreviatedName: EN.ON
+ description: ST
+ identifier: DSET<II>
+ name: EN.ON
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
art Page
*PO-relevant
*CDEs
CancerGrid Query Service
Free Text
Classification
Controls
EVS-DescLogicConcept
person
Query completed.
Search
Results
CTCAE Grade 1 Personality and Behavioral Change
CTCAE Grade 2 Personality and Behavioral Change
CTCAE Grade 3 Personality and Behavioral Change
CTCAE Grade 4 Personality and Behavioral Change
CTCAE Grade 5 Personality and Behavioral Change
Chairperson
Contact Person
Person Contact Information
Person Name
Other Personal Medical History
Passive-Aggressive Personality
Person
Person Info
Person Observer
Person Observer Organization Name
Person Observer Role in Organization
<<
>>
Use
Details
A single human being.


m: "PO-relevant" created: 7/21/2008 10:19:16 AM modified: 7/21/2008 10:30:43 AM 100% 850 x 1098
BiologicEntity
Person
+ academicDegree: DSET<CD>
+ deathIndicator: BL
+ educationLevelCode: CD
+ ethnicGroupCode: DSET<CD>
+ identifier: II
+ initials: ST
+ maritalStatusCode: CD
+ name: EN.PN
+ occupationDateRange: IVL<TS>
+ postalAddress: AD
+ primaryOccupationCode: CD
+ raceCode: DSET<CD>
+ telecomAddress: DSET<TEL>
plays / is pl
Organization
abbreviatedName: EN.ON
description: ST
identifier: DSET<II>
name: EN.ON
postalAddress: AD
statusCode: CD
statusDateRange: IVL<TS>
telecomAddress: DSET<TEL>
typeCode: CD
Class : Person
General
Detail
Require
Constraints
Link
Scenario
Files
Name: Person
Stereotype:
Abstract
Author:
Status: Proposed
Scope: Public
Complexity: Easy
Alias:
Language: Java
Persistence
Keywords:
Phase: 1.0
Version: 1.0
Advanced
Notes:
A human being. (ConceptRefs: [C25190])
Apply
OK
Cancel
Help
CancerGrid Query Service
Free Text
Classification
Controls
EVS-DescLogicConcept
person
Query completed.
Search
Results
CTCAE Grade 1 Personality and Behavioral Change
CTCAE Grade 2 Personality and Behavioral Change
CTCAE Grade 3 Personality and Behavioral Change
CTCAE Grade 4 Personality and Behavioral Change
CTCAE Grade 5 Personality and Behavioral Change
Chairperson
Person Contact Information
Person Name
Other Personal Medical History
Passive-Aggressive Personality
Person
Person Info
Person Observer
Person Observer Organization Name
Person Observer Role in Organization
<<
>>
Use
Details
Definition
Props/Values
A single human being.

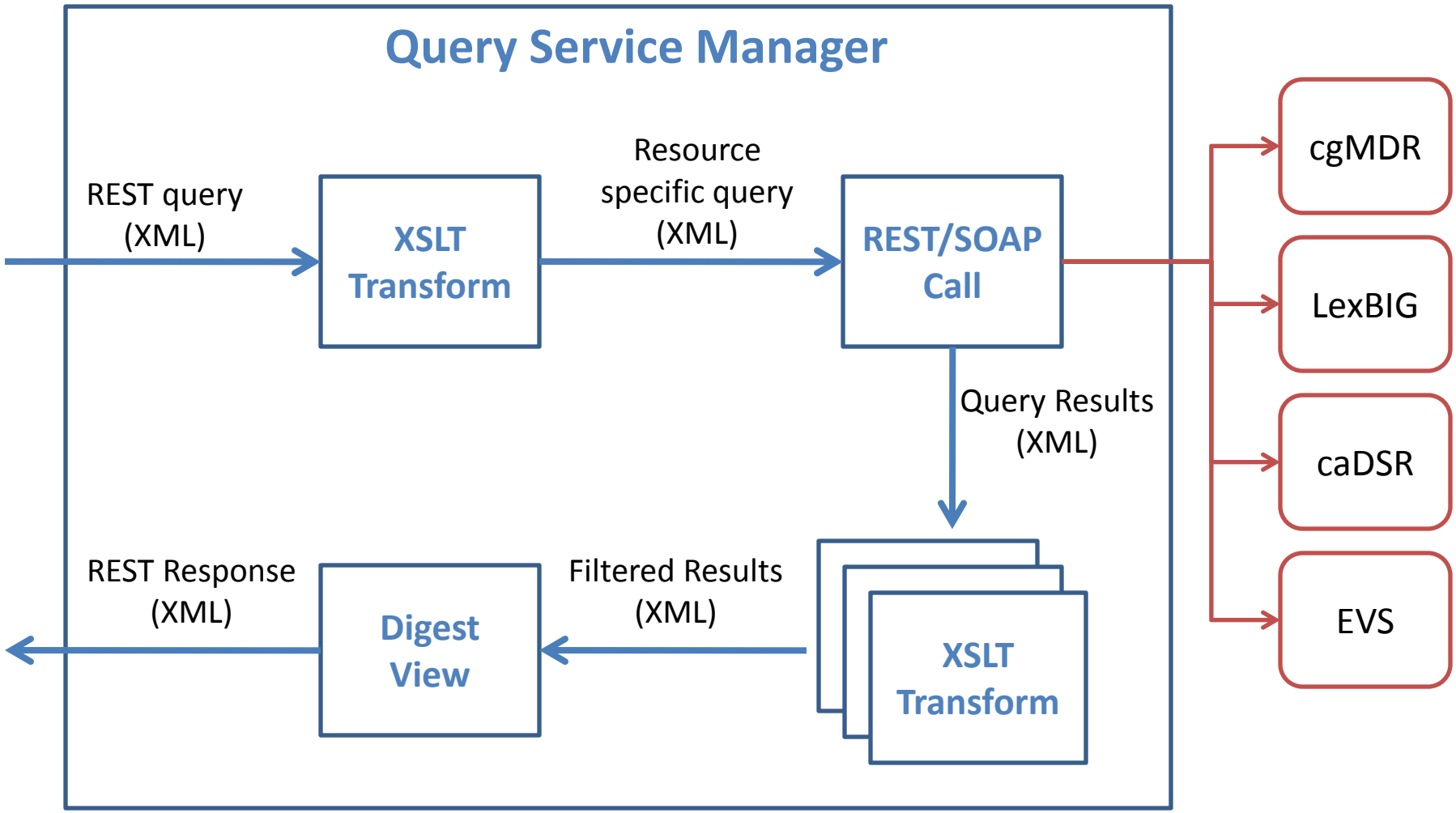

cgMDR - EA
View
Project
Diagram
Element
Tools
Add-Ins
All
iagram: "PO-relevant" created: 7/21/2008 10:19:16 AM
BiologicEntity
+ academicDegree: DSET<CD>
+ deathIndicator: BL
+ educationLevelCode: CD
+ ethnicGroupCode: DSET<CD>
+ identifier: II
+ initials: ST
+ maritalStatusCode: CD
+ name: EN.PN
+ occupationDateRange: IVL<TS>
+ postalAddress: AD
+ primaryOccupationCode: CD
+ raceCode: DSET<CD>
+ telecomAddress: DSET<TEL>
plays / is pl
Organization
+ abbreviatedName: EN.ON
+ description: ST
+ identifier: DSET<II>
+ name: EN.ON
+ postalAddress: AD
+ statusCode: CD
+ statusDateRange: IVL<TS>
+ telecomAddress: DSET<TEL>
+ typeCode: CD
art Page
*PO-relevant
*CDEs
CancerGrid Query Service
Free Text
Classification
Controls
caDSR
academic degree
Query completed.
Search
Results
DENT_ACADDGR_TXT
P_ACD_DEG_SF_ABR_TXT
T_OC_ACAD_DEG_SUF_CD
HCP_AC_DG_SF_ABR_TXT
<<
>>
Use
Details
Definition
Props/Values
Code
Meaning
MD
Doctor of Medicine
DO
Doctor of Osteopathic Medicine
DMD
Doctor of Dental Medicine
DED
Doctor of Education
DD
Doctor of Divinity
DC
Doctor of Chiropractic

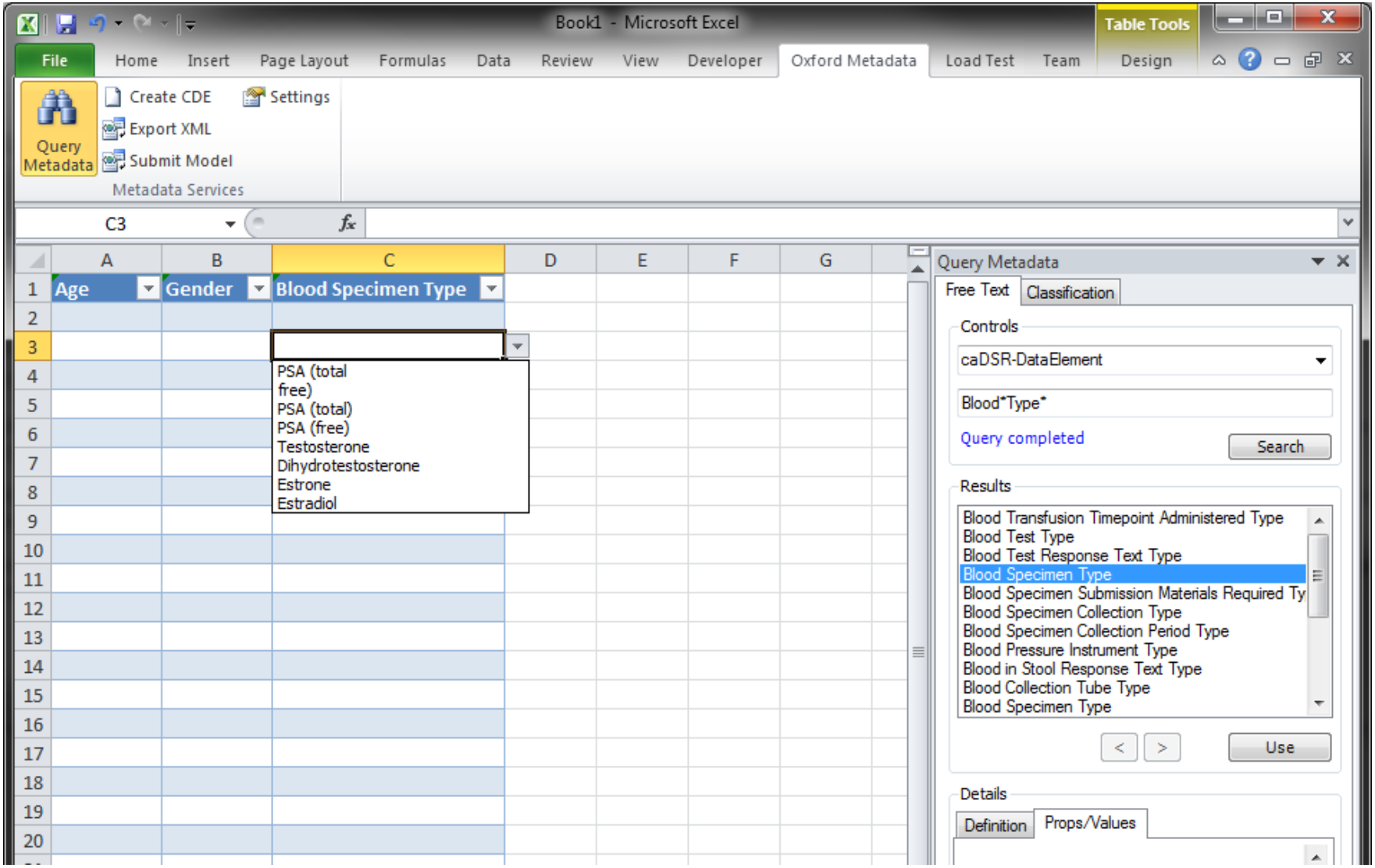
# behind the scenes

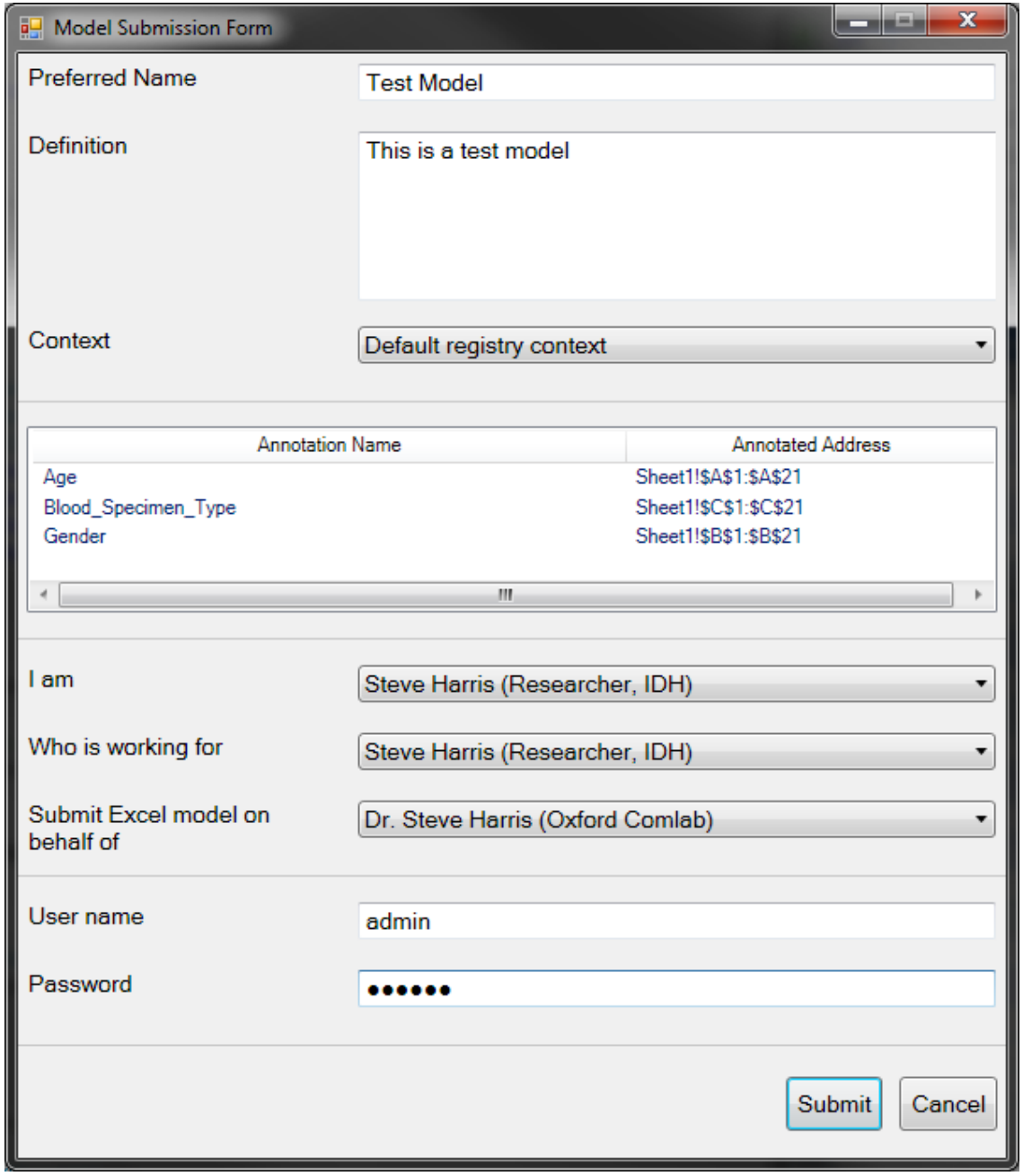


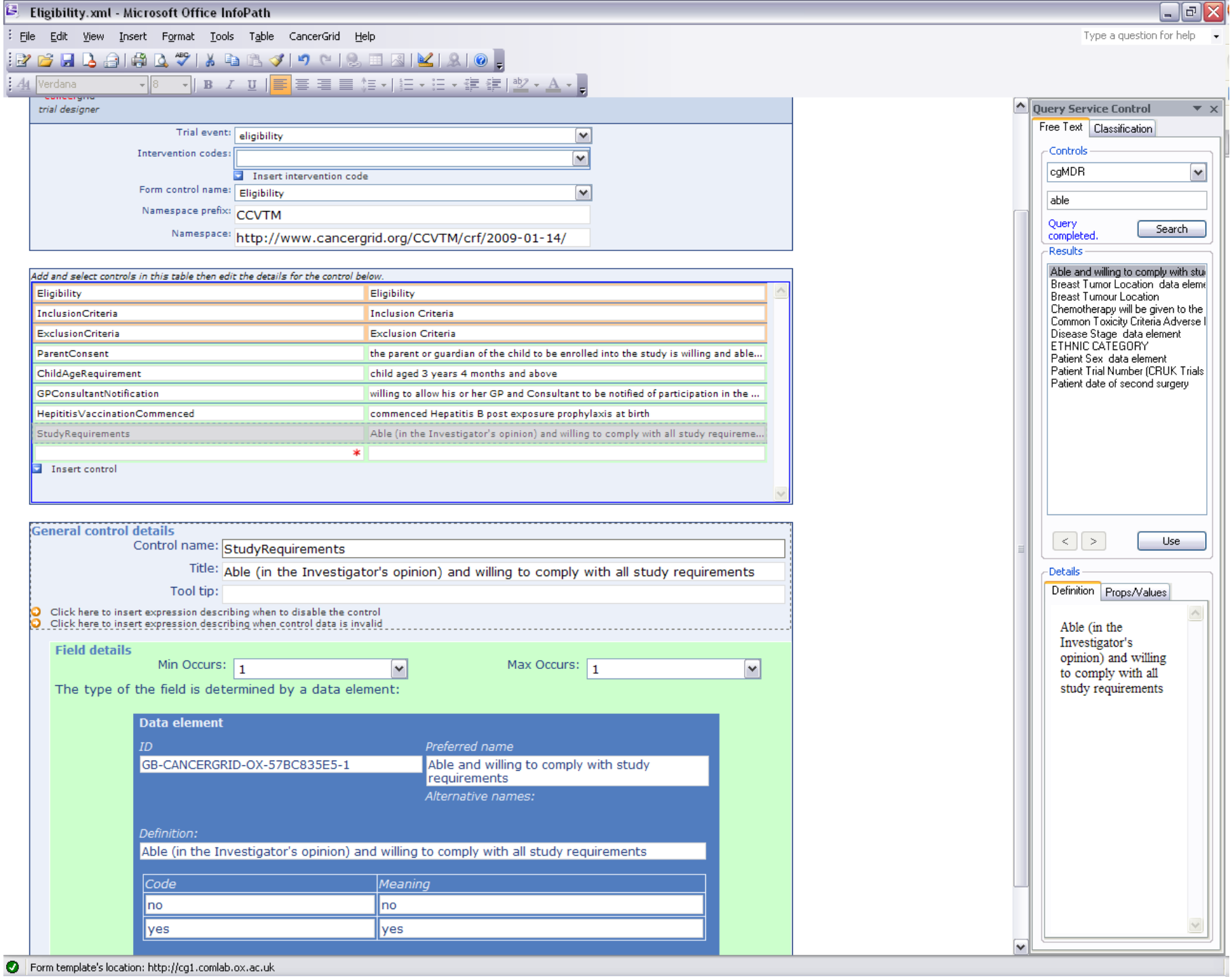



# query service manager



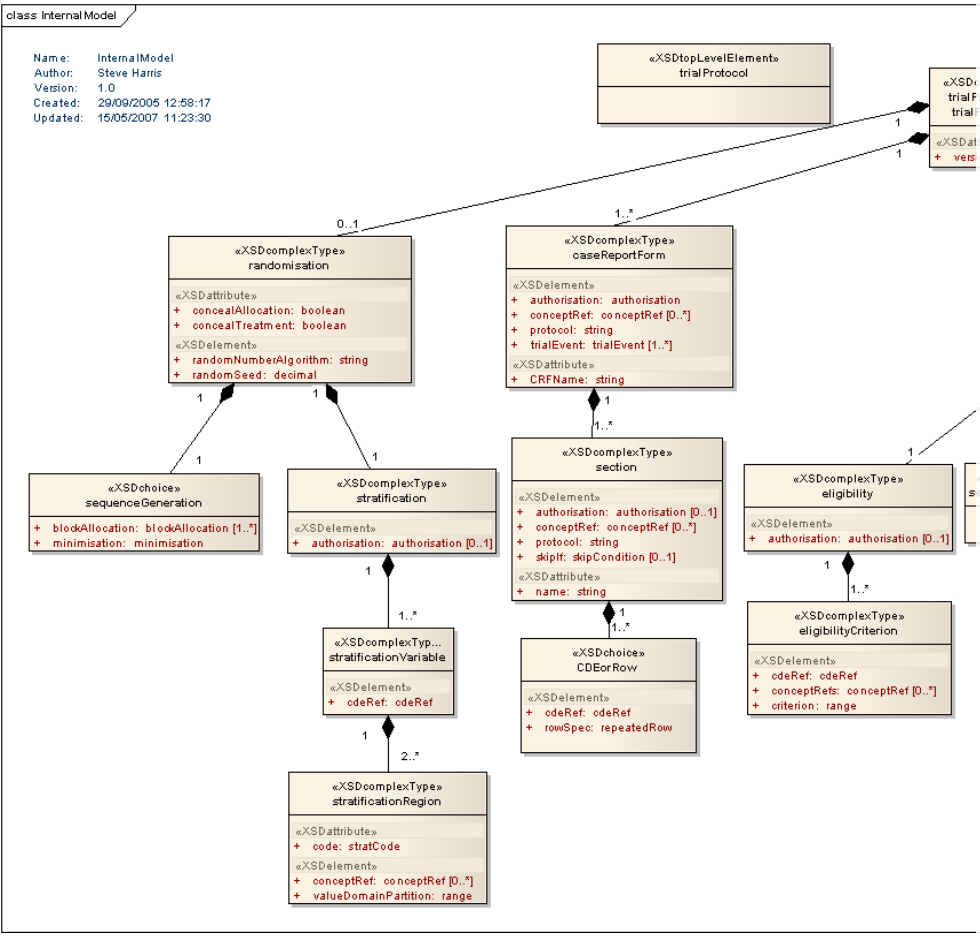

Book1 - Microsoft Excel
Table Tools
File
Home
Insert
Page Layout
Formulas
Data
Review
View
Developer
Oxford Metadata
Load Test
Team
Design
Query Metadata
Create CDE
Settings
Export XML
Submit Model
Metadata Services
C3
Age
Gender
Blood Specimen Type
PSA (total
free)
PSA (total)
PSA (free)
Testosterone
Dihydrotestosterone
Estrone
Estradiol
Query Metadata
Free Text
Classification
Controls
caDSR-DataElement
Blood*Type*
Query completed
Search
Results
Blood Transfusion Timepoint Administered Type
Blood Test Type
Blood Test Response Text Type
Blood Specimen Type
Blood Specimen Submission Materials Required Ty
Blood Specimen Collection Type
Blood Specimen Collection Period Type
Blood Pressure Instrument Type
Blood in Stool Response Text Type
Blood Collection Tube Type
Blood Specimen Type
Use
Details
Definition
Props/Values


Model Submission Form
Preferred Name
Test Model
Definition
This is a test model
Context
Default registry context
Annotation Name
Annotated Address
Age
Sheet1!$A$1:$A$21
Blood_Specimen_Type
Sheet1!$C$1:$C$21
Gender
Sheet1!$B$1:$B$21
I am
Steve Harris (Researcher, IDH)
Who is working for
Steve Harris (Researcher, IDH)
Submit Excel model on behalf of
Dr. Steve Harris (Oxford Comlab)
User name
admin
Password
Submit
Cancel

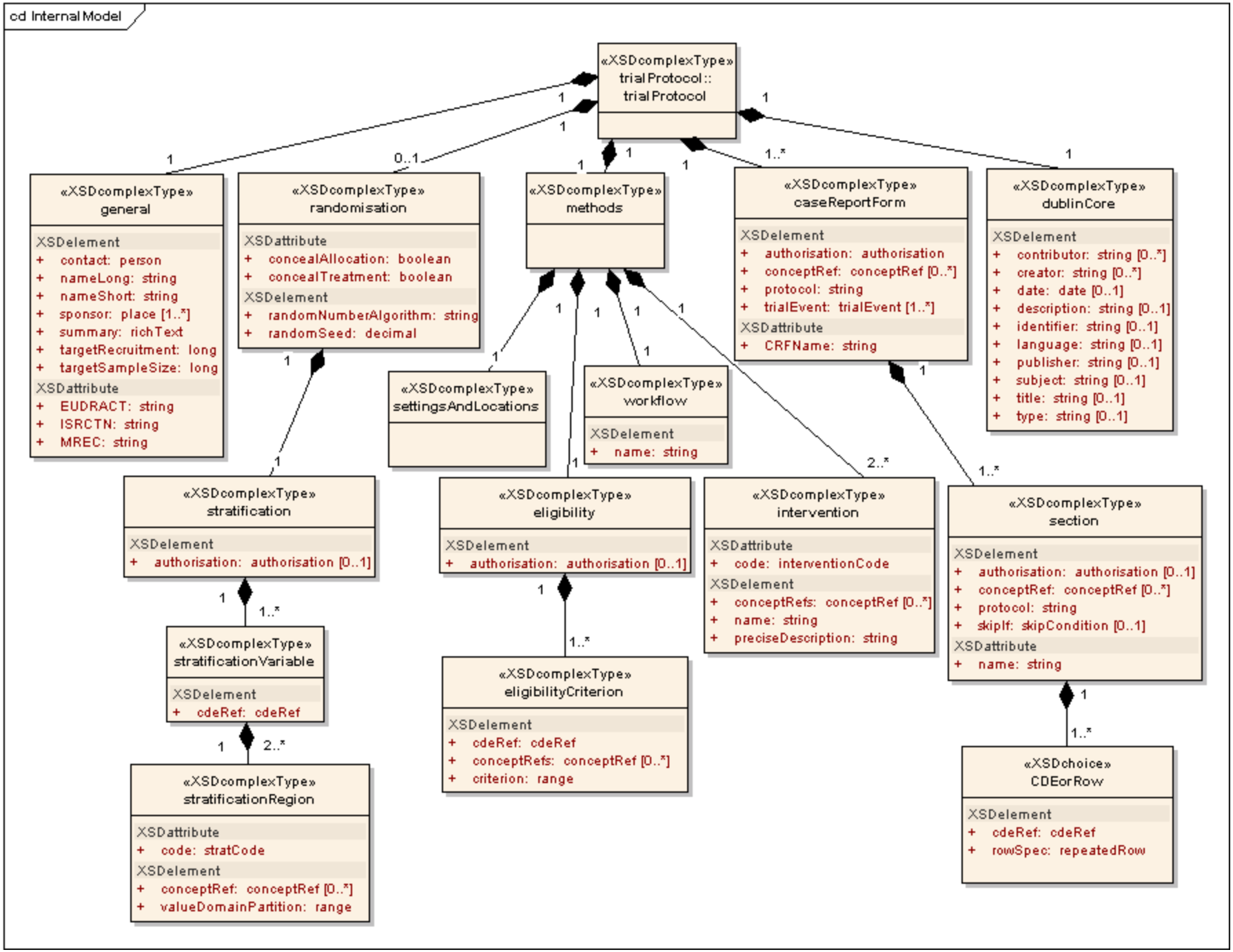

Eligibility.xml - Microsoft Office InfoPath
File Edit View Insert Format Tools Table CancerGrid Help
Type a question for help
trial designer
Trial event: eligibility
Intervention codes:
Insert intervention code
Form control name: Eligibility
Namespace prefix: CCVTM
Namespace: http://www.cancergrid.org/CCVTM/crf/2009-01-14/
Add and select controls in this table then edit the details for the control below.
Eligibility | Eligibility
InclusionCriteria | Inclusion Criteria
ExclusionCriteria | Exclusion Criteria
ParentConsent | the parent or guardian of the child to be enrolled into the study is willing and able...
ChildAgeRequirement | child aged 3 years 4 months and above
GPConsultantNotification | willing to allow his or her GP and Consultant to be notified of participation in the ...
HepititisVaccinationCommenced | commenced Hepatitis B post exposure prophylaxis at birth
StudyRequirements | Able (in the Investigator's opinion) and willing to comply with all study requireme...
Insert control
General control details
Control name: StudyRequirements
Title: Able (in the Investigator's opinion) and willing to comply with all study requirements
Tool tip:
Click here to insert expression describing when to disable the control
Click here to insert expression describing when control data is invalid
Field details
Min Occurs: 1
Max Occurs: 1
The type of the field is determined by a data element:
Data element
ID
GB-CANCERGRID-OX-57BC835E5-1
Preferred name
Able and willing to comply with study requirements
Alternative names:
Definition:
Able (in the Investigator's opinion) and willing to comply with all study requirements
Code | Meaning
no | no
yes | yes
Query Service Control
Free Text
Classification
Controls
cgMDR
able
Query completed.
Search
Results
Able and willing to comply with stu
Breast Tumor Location data eleme
Breast Tumour Location
Chemotherapy will be given to the
Common Toxicity Criteria Adverse I
Disease Stage data element
ETHNIC CATEGORY
Patient Sex data element
Patient Trial Number (CRUK Trials
Patient date of second surgery
Use
Details
Definition
Props/Values
Able (in the Investigator's opinion) and willing to comply with all study requirements
Form template's location: http://cg1.comlab.ox.ac.uk

# GENERATION FROM EXPERIMENTAL MODELS

# meta-models of experiments




- standardise models/designs
- support parameterisation of services or transformation into software
- combining meta-models with metadata elements removes a major source of variability from experimental designs
- support experiment designing software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trialProtocol::
trialProtocol
«XSDcomplexType»
general
XSDelement
+ contact: person
+ nameLong: string
+ nameShort: string
+ sponsor: place [1..*]
+ summary: richText
+ targetRecruitment: long
+ targetSampleSize: long
XSDattribute
+ EUDRACT: string
+ ISRCTN: string
+ MREC: string
«XSDcomplexType»
randomisation
XSDattribute
+ concealAllocation: boolean
+ concealTreatment: boolean
XSDelement
+ randomNumberAlgorithm: string
+ randomSeed: decimal
«XSDcomplexType»
methods
«XSDcomplexType»
caseReportForm
XSDelement
+ authorisation: authorisation
+ conceptRef: conceptRef [0..*]
+ protocol: string
+ trialEvent: trialEvent [1..*]
XSDattribute
+ CRFName: string
«XSDcomplexType»
dublinCore
XSDelement
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+ creator: string [0..*]
+ date: date [0..1]
+ description: string [0..1]
+ identifier: string [0..1]
+ language: string [0..1]
+ publisher: string [0..1]
+ subject: string [0..1]
+ title: string [0..1]
+ type: string [0..1]
«XSDcomplexType»
settingsAndLocations
«XSDcomplexType»
workflow
XSDelement
+ name: string
«XSDcomplexType»
stratification
XSDelement
+ authorisation: authorisation [0..1]
«XSDcomplexType»
eligibility
XSDelement
+ authorisation: authorisation [0..1]
«XSDcomplexType»
intervention
XSDattribute
+ code: interventionCode
XSDelement
+ conceptRefs: conceptRef [0..*]
+ name: string
+ preciseDescription: string
«XSDcomplexType»
section
XSDelement
+ authorisation: authorisation [0..1]
+ conceptRef: conceptRef [0..*]
+ protocol: string
+ skipIf: skipCondition [0..1]
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+ name: string
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stratificationVariable
XSDelement
+ cdeRef: cdeRef
«XSDcomplexType»
eligibilityCriterion
XSDelement
+ cdeRef: cdeRef
+ conceptRefs: conceptRef [0..*]
+ criterion: range
«XSDchoice»
CDEorRow
XSDelement
+ cdeRef: cdeRef
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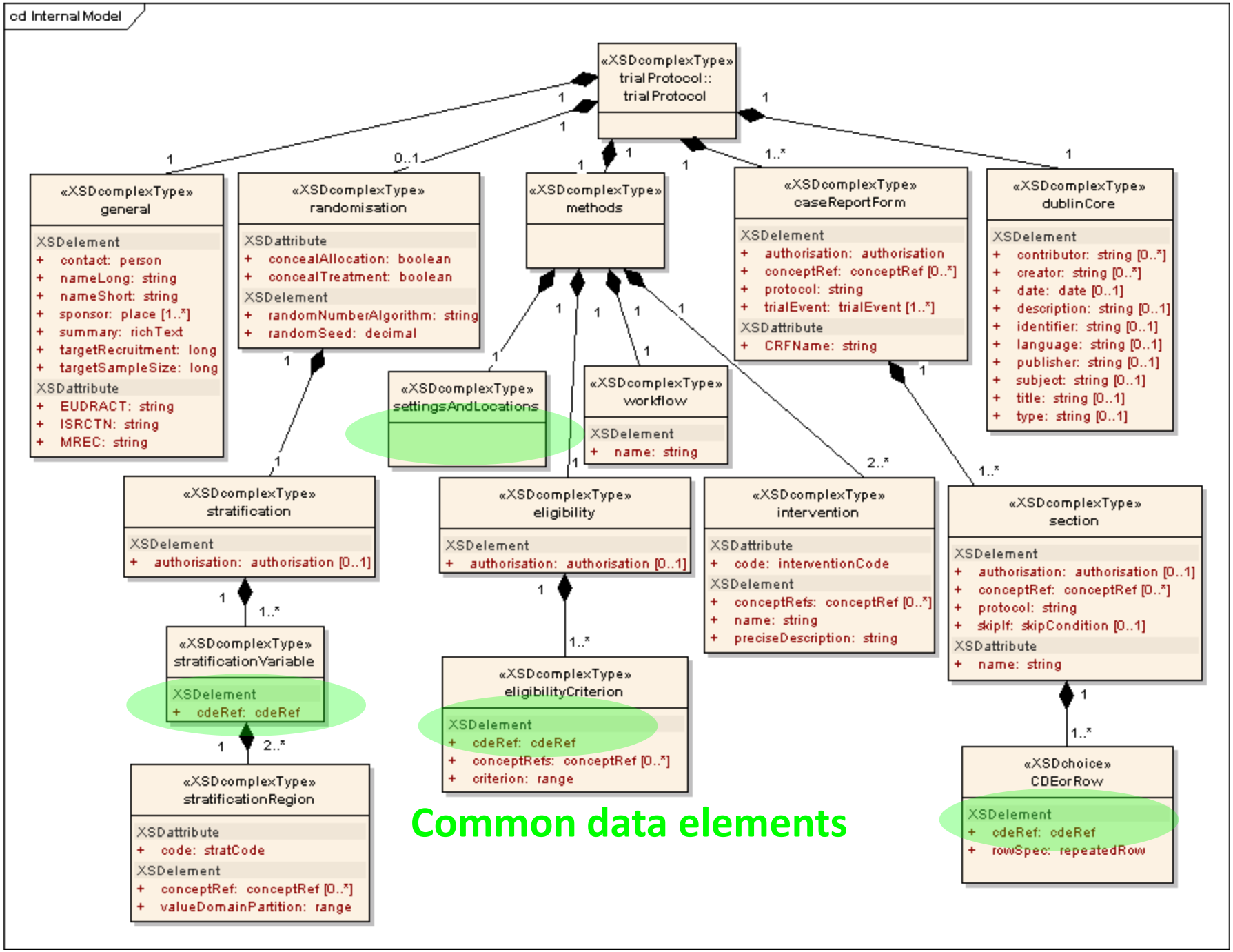
«XSDcomplexType»
stratificationRegion
XSDattribute
+ code: stratCode
XSDelement
+ conceptRef: conceptRef [0..*]
+ valueDomainPartition: range


cd Internal Model
«XSDcomplexType»
trialProtocol::
trialProtocol
«XSDcomplexType»
general
XSDelement
+ contact: person
+ nameLong: string
+ nameShort: string
+ sponsor: place [1..*]
+ summary: richText
+ targetRecruitment: long
+ targetSampleSize: long
XSDattribute
+ EUDRACT: string
+ ISRCTN: string
+ MREC: string
«XSDcomplexType»
randomisation
XSDattribute
+ concealAllocation: boolean
+ concealTreatment: boolean
XSDelement
+ randomNumberAlgorithm: string
+ randomSeed: decimal
«XSDcomplexType»
methods
«XSDcomplexType»
caseReportForm
XSDelement
+ authorisation: authorisation
+ conceptRef: conceptRef [0..*]
+ protocol: string
+ trialEvent: trialEvent [1..*]
XSDattribute
+ CRFName: string
«XSDcomplexType»
dublinCore
XSDelement
+ contributor: string [0..*]
+ creator: string [0..*]
+ date: date [0..1]
+ description: string [0..1]
+ identifier: string [0..1]
+ language: string [0..1]
+ publisher: string [0..1]
+ subject: string [0..1]
+ title: string [0..1]
+ type: string [0..1]
«XSDcomplexType»
settingsAndLocations
«XSDcomplexType»
workflow
XSDelement
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intervention
XSDattribute
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XSDelement
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section
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«XSDchoice»
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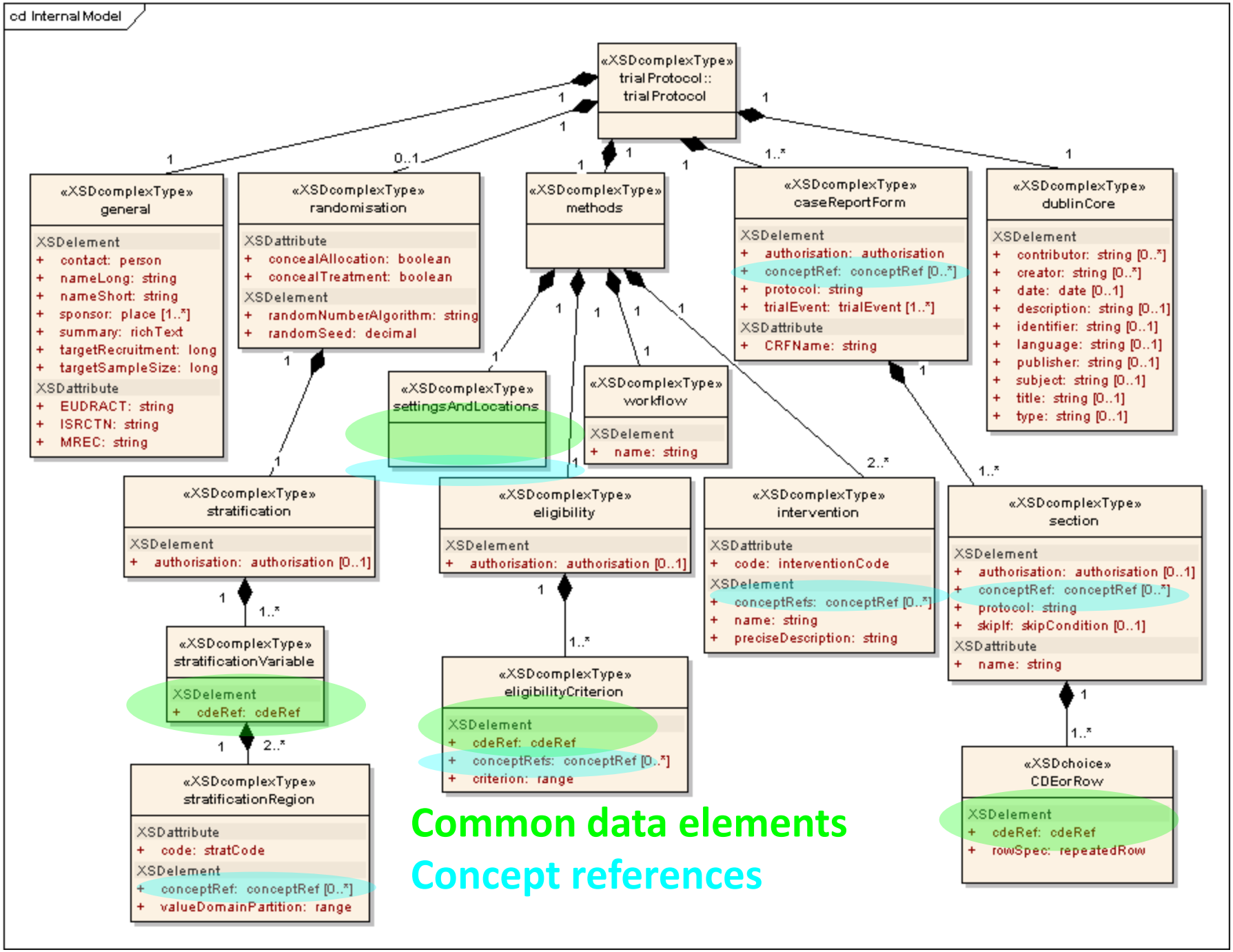
XSDelement
+ cdeRef: cdeRef
+ rowSpec: repeatedRow
Common data elements


cd Internal Model
«XSDcomplexType»
trialProtocol::
trialProtocol
«XSDcomplexType»
general
XSDelement
+ contact: person
+ nameLong: string
+ nameShort: string
+ sponsor: place [1..*]
+ summary: richText
+ targetRecruitment: long
+ targetSampleSize: long
XSDattribute
+ EUDRACT: string
+ ISRCTN: string
+ MREC: string
«XSDcomplexType»
randomisation
XSDattribute
+ concealAllocation: boolean
+ concealTreatment: boolean
XSDelement
+ randomNumberAlgorithm: string
+ randomSeed: decimal
«XSDcomplexType»
methods
«XSDcomplexType»
caseReportForm
XSDelement
+ authorisation: authorisation
+ conceptRef: conceptRef [0..*]
+ protocol: string
+ trialEvent: trialEvent [1..*]
XSDattribute
+ CRFName: string
«XSDcomplexType»
dublinCore
XSDelement
+ contributor: string [0..*]
+ creator: string [0..*]
+ date: date [0..1]
+ description: string [0..1]
+ identifier: string [0..1]
+ language: string [0..1]
+ publisher: string [0..1]
+ subject: string [0..1]
+ title: string [0..1]
+ type: string [0..1]
«XSDcomplexType»
settingsAndLocations
«XSDcomplexType»
workflow
XSDelement
+ name: string
«XSDcomplexType»
stratification
XSDelement
+ authorisation: authorisation [0..1]
«XSDcomplexType»
eligibility
XSDelement
+ authorisation: authorisation [0..1]
«XSDcomplexType»
intervention
XSDattribute
+ code: interventionCode
XSDelement
+ conceptRefs: conceptRef [0..*]
+ name: string
+ preciseDescription: string
«XSDcomplexType»
section
XSDelement
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+ conceptRef: conceptRef [0..*]
+ protocol: string
+ skipIf: skipCondition [0..1]
XSDattribute
+ name: string
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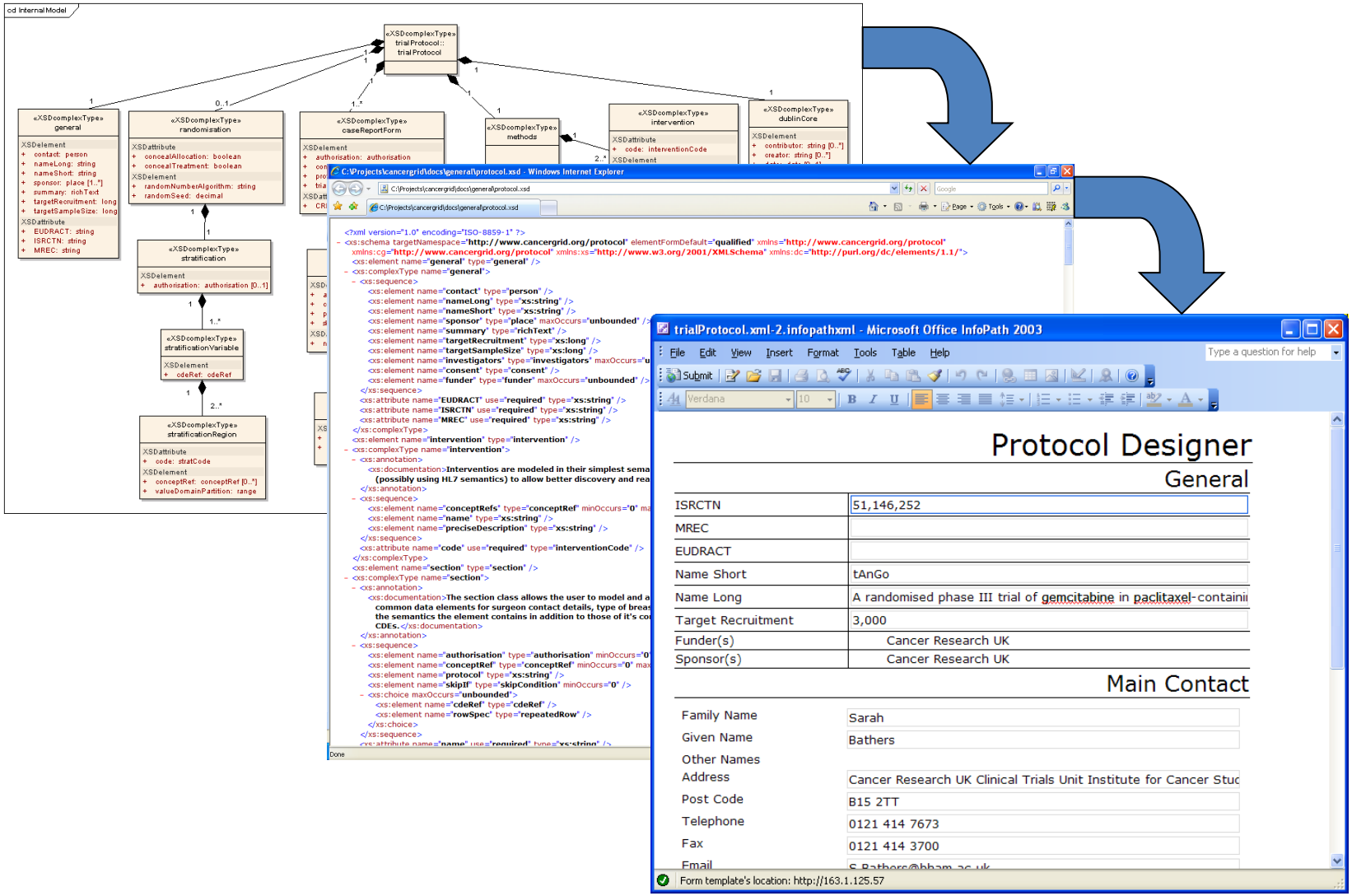
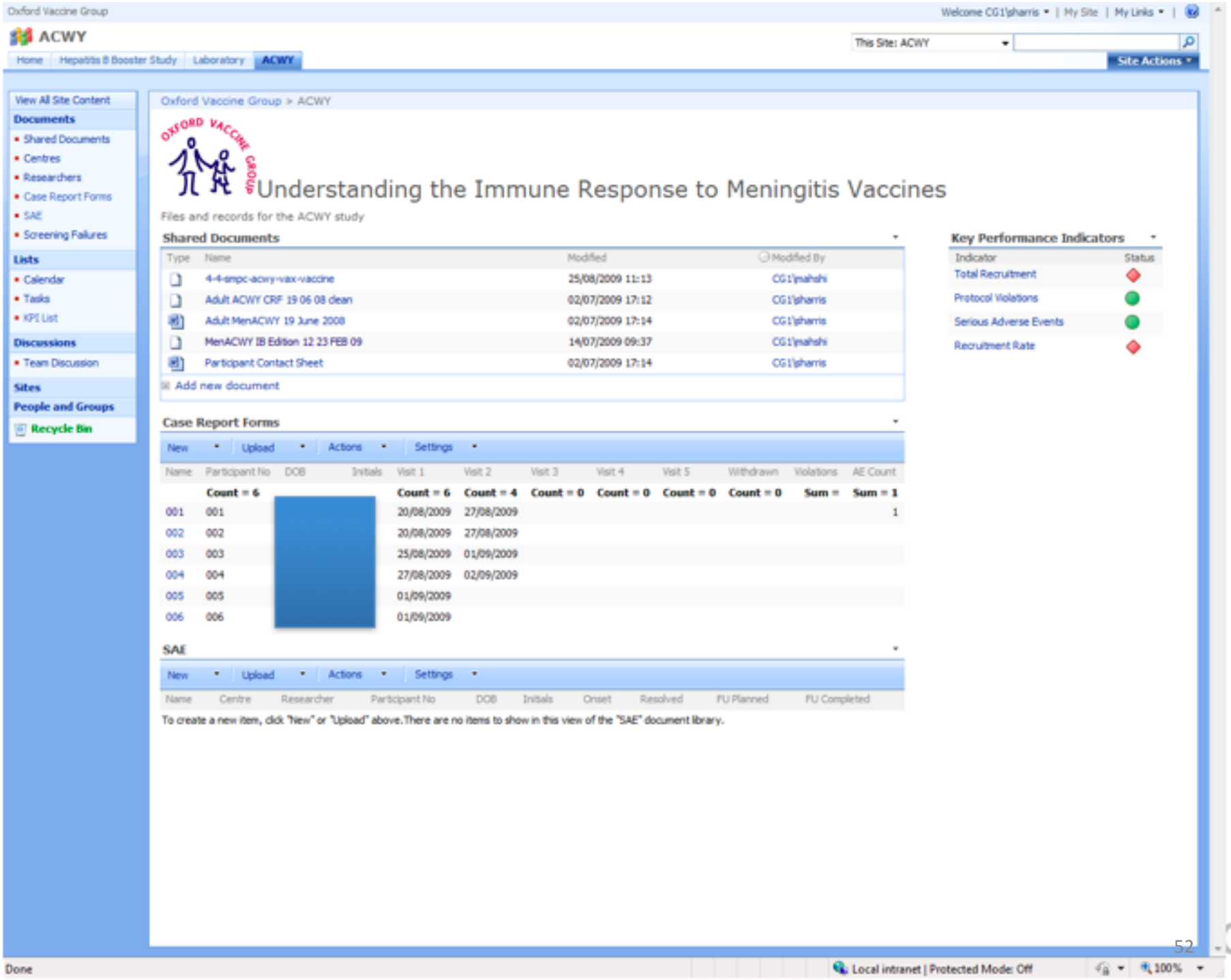
stratificationVariable
XSDelement
+ cdeRef: cdeRef
«XSDcomplexType»
eligibilityCriterion
XSDelement
+ cdeRef: cdeRef
+ conceptRefs: conceptRef [0..*]
+ criterion: range
«XSDcomplexType»
stratificationRegion
XSDattribute
+ code: stratCode
XSDelement
+ conceptRef: conceptRef [0..*]
+ valueDomainPartition: range
«XSDchoice»
CDEorRow
XSDelement
+ cdeRef: cdeRef
+ rowSpec: repeatedRow
Common data elements
Concept references

# user interface generation




Oxford Vaccine Group
Welcome CG1\pharris | My Site | My Links |
ACWY
This Site: ACWY
Site Actions
Home
Hepatitis B Booster Study
Laboratory
ACWY
View All Site Content
Documents
Shared Documents
Centres
Researchers
Case Report Forms
SAE
Screening Failures
Lists
Calendar
Tasks
KPI List
Discussions
Team Discussion
Sites
People and Groups
Recycle Bin
Oxford Vaccine Group > ACWY
OXFORD VACCINE GROUP
Understanding the Immune Response to Meningitis Vaccines
Files and records for the ACWY study
Shared Documents
Type Name Modified Modified By
4-4-smpc-acwy-vax-vaccine 25/08/2009 11:13 CG1\mahshi
Adult ACWY CRF 19 06 08 clean 02/07/2009 17:12 CG1\pharris
Adult MenACWY 19 June 2008 02/07/2009 17:14 CG1\pharris
MenACWY IB Edition 12 23 FEB 09 14/07/2009 09:37 CG1\mahshi
Participant Contact Sheet 02/07/2009 17:14 CG1\pharris
Add new document
Key Performance Indicators
Indicator Status
Total Recruitment
Protocol Violations
Serious Adverse Events
Recruitment Rate
Case Report Forms
New Upload Actions Settings
Name Participant No DOB Initials Visit 1 Visit 2 Visit 3 Visit 4 Visit 5 Withdrawn Violations AE Count
Count = 6 Count = 6 Count = 4 Count = 0 Count = 0 Count = 0 Count = 0 Sum = Sum = 1
001 001 20/08/2009 27/08/2009 1
002 002 20/08/2009 27/08/2009
003 003 25/08/2009 01/09/2009
004 004 27/08/2009 02/09/2009
005 005 01/09/2009
006 006 01/09/2009
SAE
New Upload Actions Settings
Name Centre Researcher Participant No DOB Initials Onset Resolved FU Planned FU Completed
To create a new item, click "New" or "Upload" above. There are no items to show in this view of the "SAE" document library.
Done
Local intranet | Protected Mode: Off
100%

# Hepatitis B Booster Study



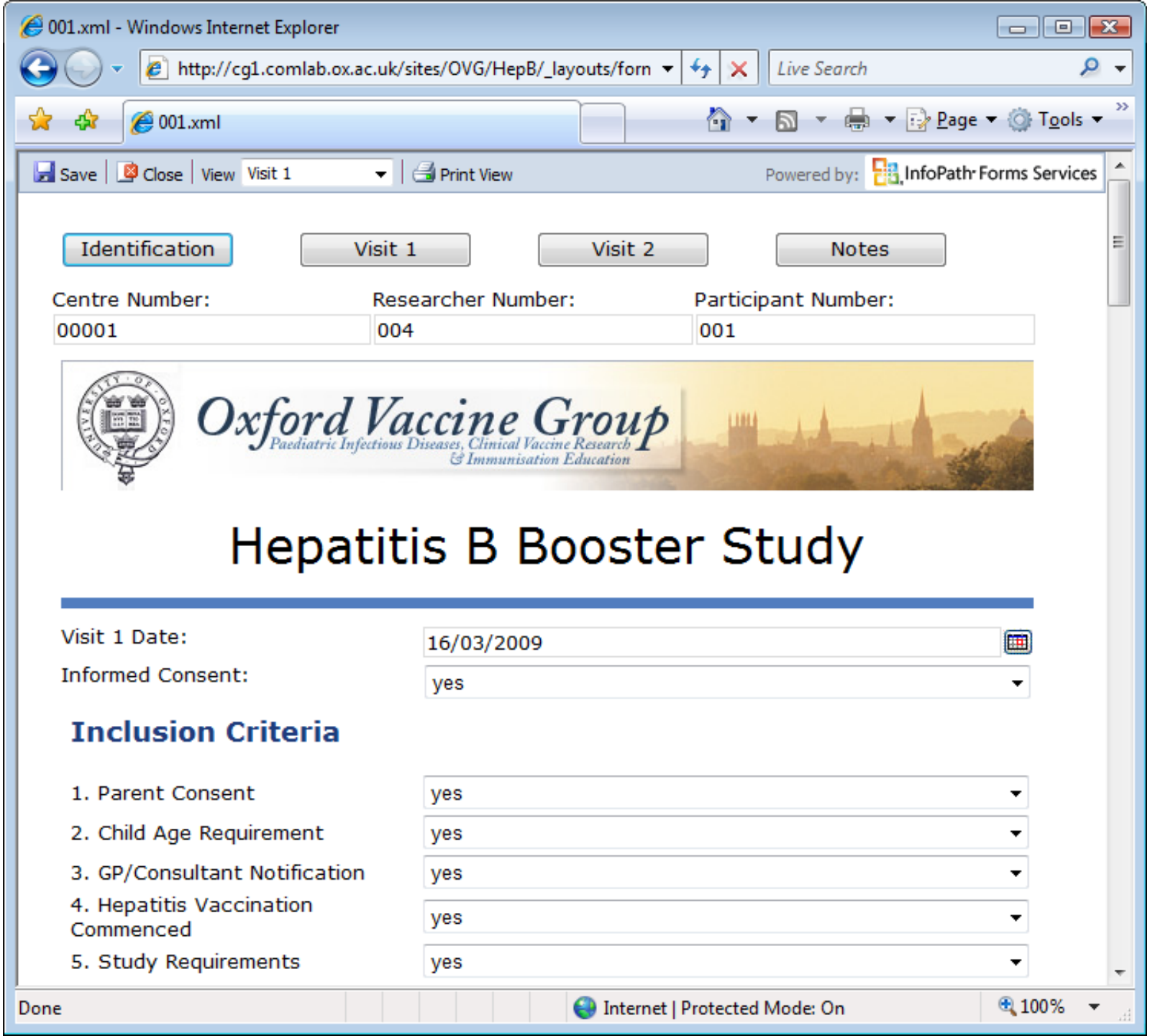

## Shared Documents

| Type | Name | Modified By |
|---|---|---|
| | Source Document | CG1\vgtest |
| | Parent Contact Sheet | CG1\vgtest |
| | Hepatitis B protocol -24th Oct 2008 | CG1\sharris |

Add new document

## Participant Status

| Centre Number | Researcher Number | Participant Number | Visit 1 Date | Visit 2 Date | Planned V 2 Date | Participant Initials |
|---|---|---|---|---|---|---|
| 00001 | 004 | 001 | 3/16/2009 12:00 AM | | | AB |


001.xml - Windows Internet Explorer
http://cg1.comlab.ox.ac.uk/sites/OVG/HepB/_layouts/forn
Live Search
001.xml
Page
Tools
Save
Close
View
Visit 1
Print View
Powered by:
InfoPath Forms Services
Identification
Visit 1
Visit 2
Notes
Centre Number:
00001
Researcher Number:
004
Participant Number:
001
Oxford Vaccine Group
Paediatric Infectious Diseases, Clinical Vaccine Research & Immunisation Education
Hepatitis B Booster Study
Visit 1 Date:
16/03/2009
Informed Consent:
yes
Inclusion Criteria
1. Parent Consent
yes
2. Child Age Requirement
yes
3. GP/Consultant Notification
yes
4. Hepatitis Vaccination Commenced
yes
5. Study Requirements
yes
Done
Internet | Protected Mode: On
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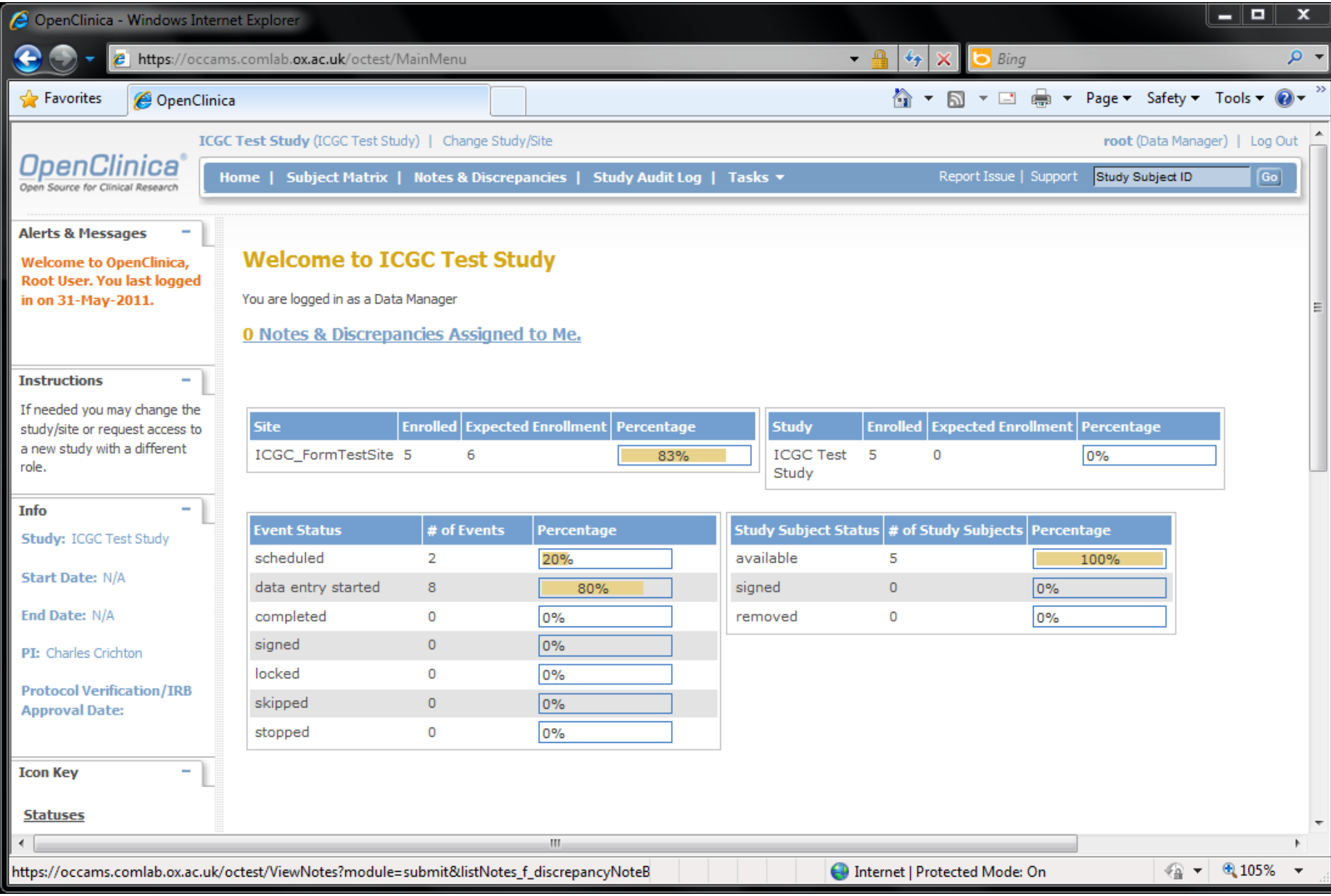
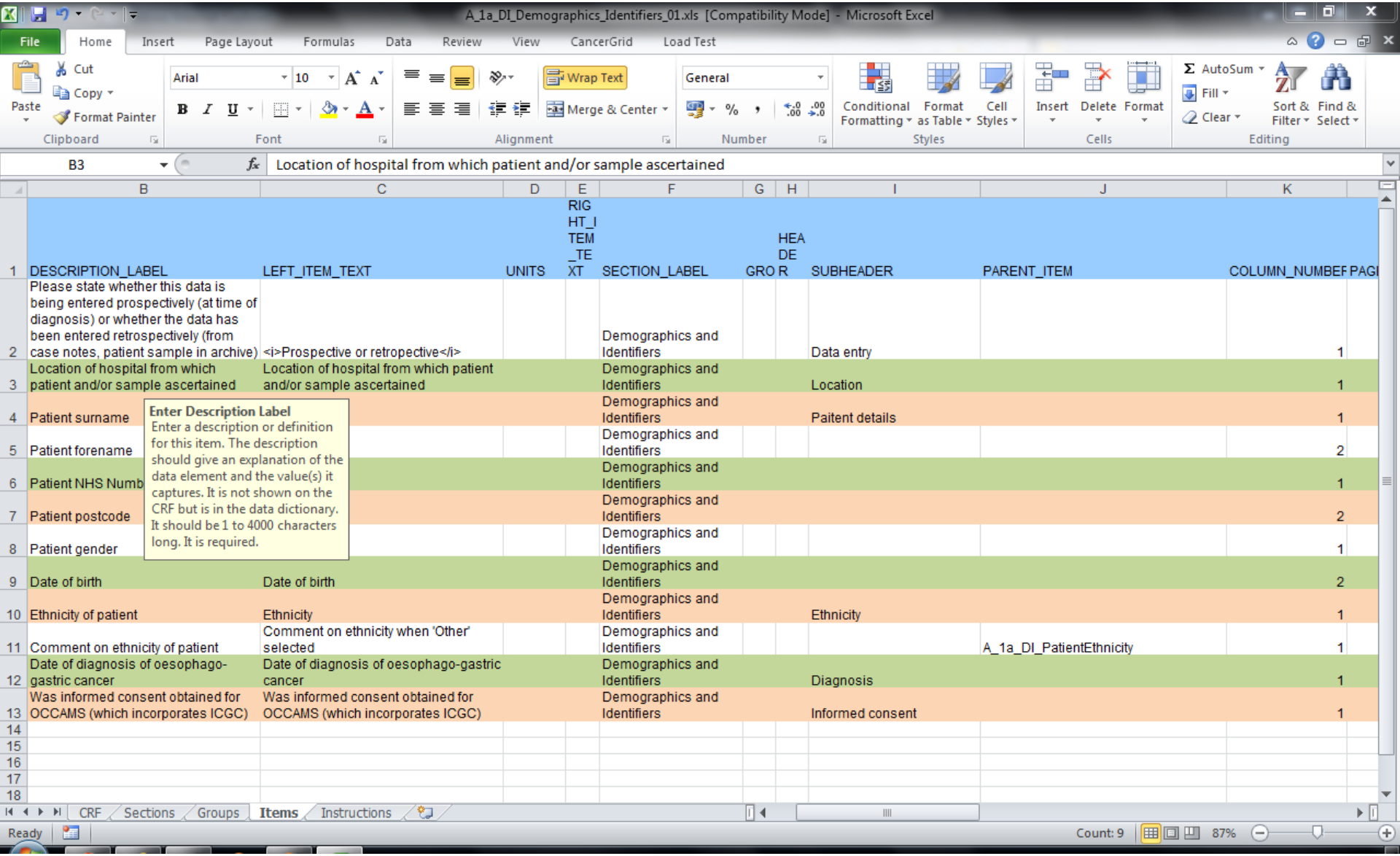
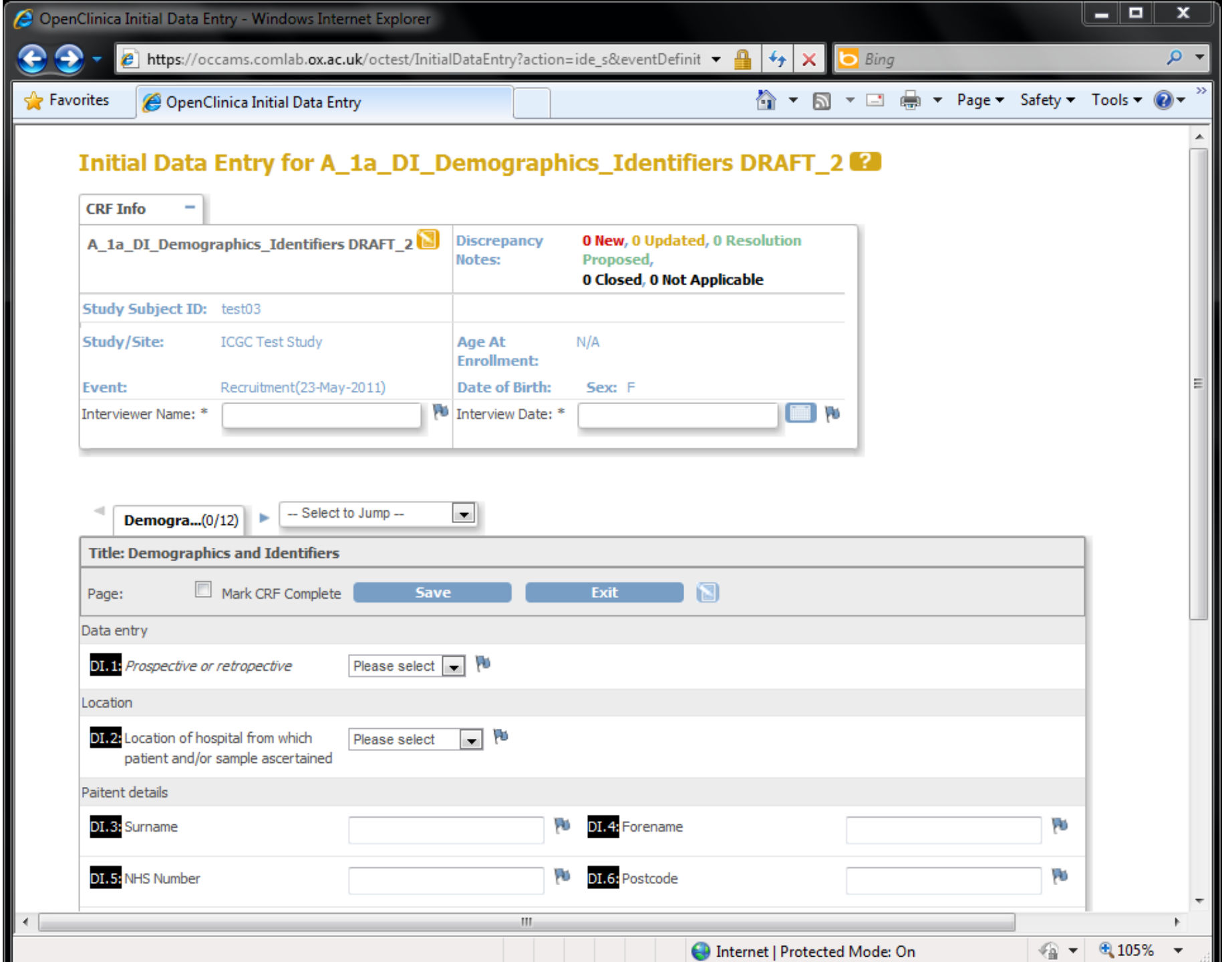
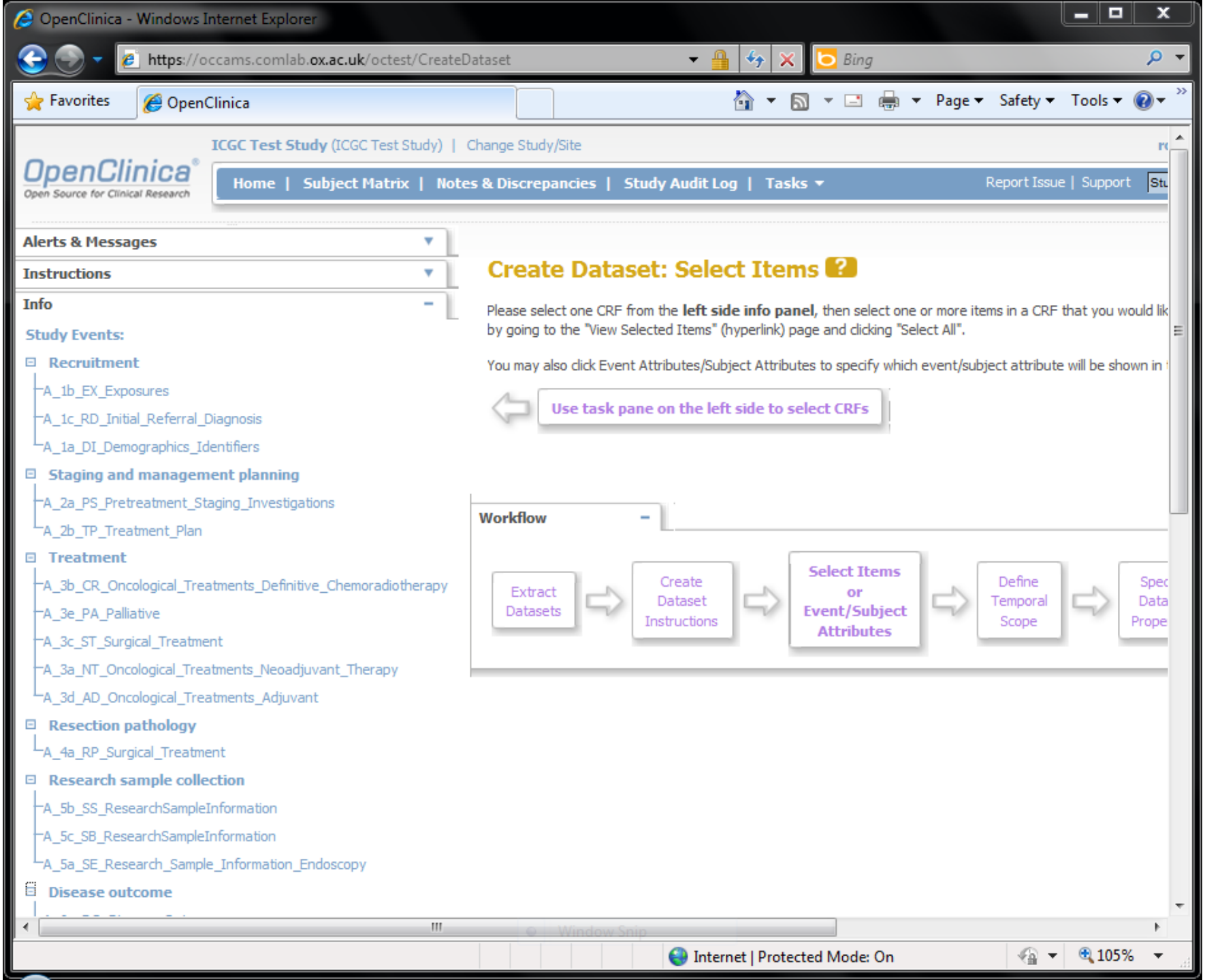

OpenClinica - Windows Internet Explorer
https://occams.comlab.ox.ac.uk/octest/MainMenu
Bing
Favorites
OpenClinica
Page
Safety
Tools
ICGC Test Study (ICGC Test Study) | Change Study/Site
root (Data Manager) | Log Out
OpenClinica
Open Source for Clinical Research
Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks
Report Issue | Support
Study Subject ID
Go
Alerts & Messages
Welcome to OpenClinica, Root User. You last logged in on 31-May-2011.
Instructions
If needed you may change the study/site or request access to a new study with a different role.
Info
Study: ICGC Test Study
Start Date: N/A
End Date: N/A
PI: Charles Crichton
Protocol Verification/IRB Approval Date:
Icon Key
Statuses
Welcome to ICGC Test Study
You are logged in as a Data Manager
0 Notes & Discrepancies Assigned to Me.
Site
Enrolled
Expected Enrollment
Percentage
ICGC_FormTestSite 5 6 83%
Study
Enrolled
Expected Enrollment
Percentage
ICGC Test Study 5 0 0%
Event Status
# of Events
Percentage
scheduled 2 20%
data entry started 8 80%
completed 0 0%
signed 0 0%
locked 0 0%
skipped 0 0%
stopped 0 0%
Study Subject Status
# of Study Subjects
Percentage
available 5 100%
signed 0 0%
removed 0 0%
https://occams.comlab.ox.ac.uk/octest/ViewNotes?module=submit&listNotes_f_discrepancyNoteB
Internet | Protected Mode: On
105%




| | B | C | D | E | F | G | H | I | J | K |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | DESCRIPTION_LABEL | LEFT_ITEM_TEXT | UNITS | RIGHT_ITEM_TEXT | SECTION_LABEL | GROUP | HEADER | SUBHEADER | PARENT_ITEM | COLUMN_NUMBER PAGE |
| 2 | Please state whether this data is being entered prospectively (at time of diagnosis) or whether the data has been entered retrospectively (from case notes, patient sample in archive) | Prospective or retropective | | | Demographics and Identifiers | | | Data entry | | 1 |
| 3 | Location of hospital from which patient and/or sample ascertained | Location of hospital from which patient and/or sample ascertained | | | Demographics and Identifiers | | | Location | | 1 |
| 4 | Patient surname | | | | Demographics and Identifiers | | | Paitent details | | 1 |
| 5 | Patient forename | | | | Demographics and Identifiers | | | | | 2 |
| 6 | Patient NHS Numb | | | | Demographics and Identifiers | | | | | 1 |
| 7 | Patient postcode | | | | Demographics and Identifiers | | | | | 2 |
| 8 | Patient gender | | | | Demographics and Identifiers | | | | | 1 |
| 9 | Date of birth | Date of birth | | | Demographics and Identifiers | | | | | 2 |
| 10 | Ethnicity of patient | Ethnicity | | | Demographics and Identifiers | | | Ethnicity | | 1 |
| 11 | Comment on ethnicity of patient | Comment on ethnicity when 'Other' selected | | | Demographics and Identifiers | | | | A_1a_DI_PatientEthnicity | 1 |
| 12 | Date of diagnosis of oesophago-gastric cancer | Date of diagnosis of oesophago-gastric cancer | | | Demographics and Identifiers | | | Diagnosis | | 1 |
| 13 | Was informed consent obtained for OCCAMS (which incorporates ICGC) | Was informed consent obtained for OCCAMS (which incorporates ICGC) | | | Demographics and Identifiers | | | Informed consent | | 1 |
| 14 | | | | | | | | | | |
| 15 | | | | | | | | | | |
| 16 | | | | | | | | | | |
| 17 | | | | | | | | | | |
| 18 | | | | | | | | | | |


OpenClinica Initial Data Entry - Windows Internet Explorer
https://occams.comlab.ox.ac.uk/octest/InitialDataEntry?action=ide_s&eventDefinit
Bing
Favorites
OpenClinica Initial Data Entry
Page
Safety
Tools
Initial Data Entry for A_1a_DI_Demographics_Identifiers DRAFT_2
CRF Info
A_1a_DI_Demographics_Identifiers DRAFT_2
Discrepancy Notes:
0 New, 0 Updated, 0 Resolution Proposed,
0 Closed, 0 Not Applicable
Study Subject ID: test03
Study/Site: ICGC Test Study
Age At Enrollment: N/A
Event: Recruitment(23-May-2011)
Date of Birth: Sex: F
Interviewer Name: *
Interview Date: *
Demogra...(0/12)
-- Select to Jump --
Title: Demographics and Identifiers
Page:
Mark CRF Complete
Save
Exit
Data entry
DI.1: Prospective or retropective
Please select
Location
DI.2: Location of hospital from which patient and/or sample ascertained
Please select
Paitent details
DI.3: Surname
DI.4: Forename
DI.5: NHS Number
DI.6: Postcode
Internet | Protected Mode: On
105%


OpenClinica - Windows Internet Explorer
https://occams.comlab.ox.ac.uk/octest/CreateDataset
Bing
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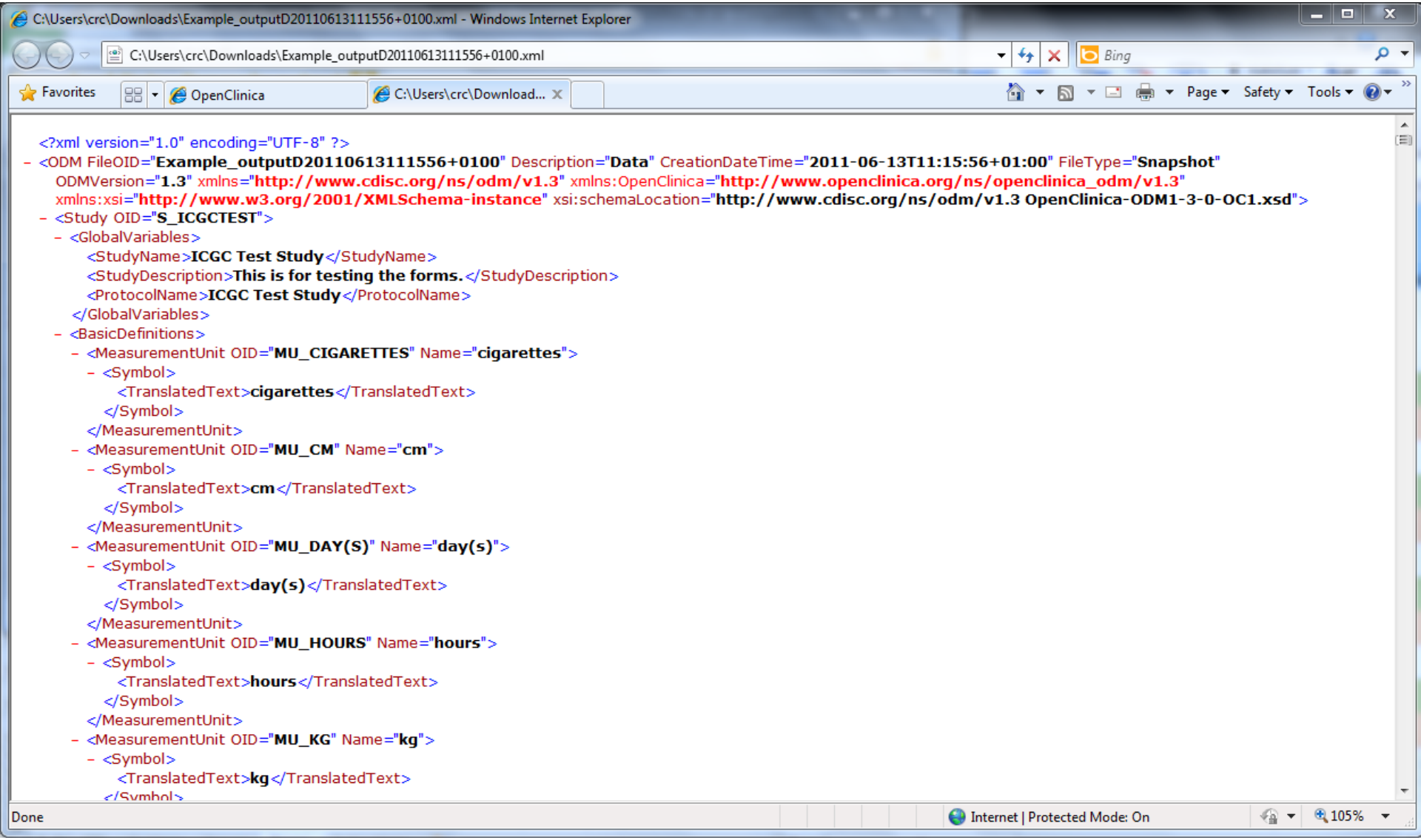
Safety
Tools
ICGC Test Study (ICGC Test Study) | Change Study/Site
OpenClinica
Open Source for Clinical Research
Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks
Report Issue | Support
Alerts & Messages
Instructions
Info
Study Events:
Recruitment
A_1b_EX_Exposures
A_1c_RD_Initial_Referral_Diagnosis
A_1a_DI_Demographics_Identifiers
Staging and management planning
A_2a_PS_Pretreatment_Staging_Investigations
A_2b_TP_Treatment_Plan
Treatment
A_3b_CR_Oncological_Treatments_Definitive_Chemoradiotherapy
A_3e_PA_Palliative
A_3c_ST_Surgical_Treatment
A_3a_NT_Oncological_Treatments_Neoadjuvant_Therapy
A_3d_AD_Oncological_Treatments_Adjuvant
Resection pathology
A_4a_RP_Surgical_Treatment
Research sample collection
A_5b_SS_ResearchSampleInformation
A_5c_SB_ResearchSampleInformation
A_5a_SE_Research_Sample_Information_Endoscopy
Disease outcome
Create Dataset: Select Items
Please select one CRF from the left side info panel, then select one or more items in a CRF that you would lik
by going to the "View Selected Items" (hyperlink) page and clicking "Select All".
You may also click Event Attributes/Subject Attributes to specify which event/subject attribute will be shown in
Use task pane on the left side to select CRFs
Workflow
Extract Datasets
Create Dataset Instructions
Select Items or Event/Subject Attributes
Define Temporal Scope
Internet | Protected Mode: On
105%


C:\Users\crc\Downloads\Example_outputD20110613111556+0100.xml - Windows Internet Explorer
C:\Users\crc\Downloads\Example_outputD20110613111556+0100.xml
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C:\Users\crc\Download...
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xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 OpenClinica-ODM1-3-0-OC1.xsd">
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<GlobalVariables>
<StudyName>ICGC Test Study</StudyName>
<StudyDescription>This is for testing the forms.</StudyDescription>
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</GlobalVariables>
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Done
Internet | Protected Mode: On
105%

# semantic frameworks

- *not enough metadata* – support the use of standards and the reuse of past experimental definitions as part of the design of systems
- *not enough data standards* – need to be available at the point of use and for use to be easier than going it alone
- *not enough data management* – generate, configure and integrate common off the shelf software, offer server resources via virtual machines and web services

## PTCRi


*Particle Therapy Cancer Research Institute*

Webpage: http://www.ptcri.ox.ac.uk/

## PARTNER



*Particle Training Network for European Radiotherapy*

Particle Therapy Marie Curie Early Initial Training Network Fellowship of the European Community's Seventh Framework Programme under contract number (PITN-GA-2008-215840-PARTNER).

Webpage: http://www.ptcri.ox.ac.uk/

## ULICE


*Union of Light Ion Centres in Europe (ULICE)*

Co-funded by the E. C. within the Framework Programme 7 Capacities Specific Programme. (*Grant Agreement 228436*).

Webpage: http://ulice.web.cern.ch