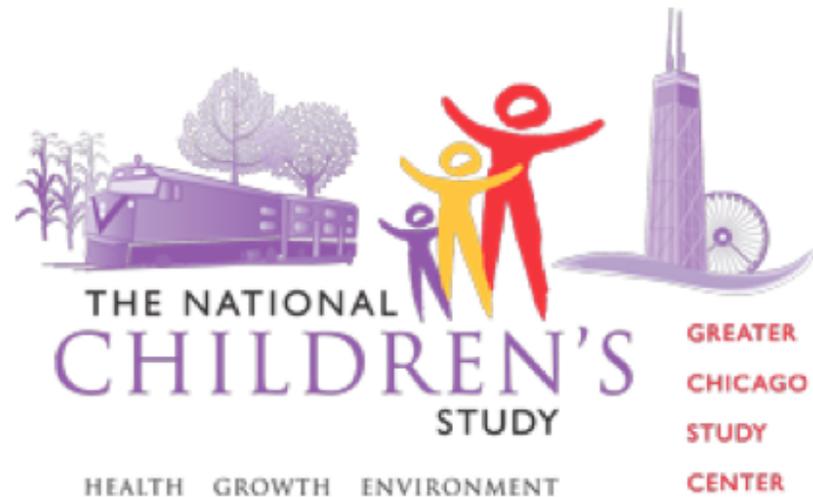


# NCS – computable elements



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<http://www.cgm.northwestern.edu/cgm/Faculty-Research/Faculty/Warren-Kibbe>

[http://wiki.bioinformatics.northwestern.edu/index.php/Warren\\_Kibbe](http://wiki.bioinformatics.northwestern.edu/index.php/Warren_Kibbe)

# Overview

MDES overview

NCS Navigator MDES Warehouse

- MDES extraction tool: [https://github.com/NUBIC/ncs\\_mdes](https://github.com/NUBIC/ncs_mdes)
- Warehouse:  
[https://github.com/NUBIC/ncs\\_mdes\\_warehouse](https://github.com/NUBIC/ncs_mdes_warehouse)

Instruments, instrument and operational elements

Versioning

Examples from the Open Biomedical Ontologies

Steps forward

# MDES

Organized into tables

Constraints are textual

Lists instruments but may not be  
comprehensive

*The next few slides highlights some  
specifics*

# MDES Data Element listing attributes

Table Type	Required Field	Length
Table Label	DE Order	Code List
Table Name	Variable Label/Definition	Status
Variable Name	Type	Table Category
PII	Numeric Type	Comments
Table Order	Format Constraint	Instrument Name

The MDES itself is incredibly useful and every multi-institutional study should have something similar to it. Better versioning, consistent constraints, and 100% consistency between the MDES and the instruments would allow rapid and nearly automated upgrades to new instruments / new versions of the MDES.

# MDES data elements

Table Type	Table Label	Table Name	Variable Name	Required Field	PII	Table Order	DE Order	Variable Label/Definition	Type	Numeric Type	Format Constraint	Length	Code List	Status	Table Category	Comments	Instrument Name
Instrument	Birth Visit	BIRTH_VISIT	MOVE_INFO	Y		101	71	Information on new address provided?	Numeric	3	1 (Address Known) 2 (Out of the country) 3 (PO Box Address only) -1 (Refused) -2 (Don't Know) -3 (Legitimate Skip) -4 (Missing in Error)		MOVING_PLA N_CL2	3		Changed to Required field.	I13 - Birth Interview (EH, PB, HI) - V1.1
Instrument	Birth Visit	BIRTH_VISIT	NEW_ADDRES S_ID	N		101	72	<b>External Identifier:</b> Identifier for NEW address record  Link to Address table.	Character		Any string of numbers and/or characters	36 chars max		1			I13 - Birth Interview (EH, PB, HI) - V1.1
Instrument	Birth Visit	BIRTH_VISIT	NEW_ADDRES S_1	N	Y	101	73	Street Address Line 1  Link to Address table.	Character		Reserved for Future Use. This field is considered PII and should be left NULL or contain the following values: -1 (Refused) -2 (Don't Know) -3 (Legitimate Skip)	100 chars max		3		Added PII text to constraint.	I13 - Birth Interview (EH, PB, HI) - V1.1

# MDES elements for Pregnancy Screener 1

Table Type	Table Label	Table Name	Variable Name	Required Field	PII	Table Order	DE Order	Variable Label/Definition	Type	Numeric Type	Format Constraint	Length	Code List	Status	Table Category	Comments	Instrument Name
Instrument	Pregnancy Visit 1	PREG_VISIT_1	PSU_ID	Y		178	1	Primary Sampling Unit Identifier  Link to PSU table.	Character		Cannot be null. Any string of numbers and/or characters.	36 chars max	<a href="#">PSU_CL1</a>	1			I9 - Pregnancy Visit 1 Interview (EH, PB, HI) - V1.0
Instrument	Pregnancy Visit 1	PREG_VISIT_1	PV1_ID	Y		178	2	Unique Identifier. PV1_ID	Character		Unique within table. Cannot be null. Any string of numbers and/or characters	36 chars max		1			I9 - Pregnancy Visit 1 Interview (EH, PB, HI) - V1.0
Instrument	Pregnancy Visit 1	PREG_VISIT_1	RECRUIT_TYPE	Y		178	3	Recruitment Strategy  Link to PSU table.	Numeric	3	1 (Enhanced Household Enumeration) 2 (Provider-Based) 3 (Two-Tier) 4 (Original VC) -4 (Missing in Error)		RECRUIT_TYPE_CL1	3		Added #4 to format constraint. Changed to required field.	I9 - Pregnancy Visit 1 Interview (EH, PB, HI) - V1.0
Instrument	Pregnancy Visit 1	PREG_VISIT_1	DU_ID	N		178	4	External Identifier: Dwelling Unit ID  Link to Dwelling Unit table.	Character		Any string of numbers and/or characters	36 chars max		1			I9 - Pregnancy Visit 1 Interview (EH, PB, HI) - V1.0
Instrument	Pregnancy Visit 1	PREG_VISIT_1	P_ID	Y		178	5	External Identifier: Participant ID  Link to Participant table.	Character		Cannot be null. Any string of numbers and/or characters.	36 chars max		1			I9 - Pregnancy Visit 1 Interview (EH, PB, HI) - V1.0
Instrument	Pregnancy	PREG_VISIT_1	EVENT_ID	Y		178	6	External	Character		Cannot be	36 chars max		1			I9 - Pregnancy

# MDES code lists

ALCOHOL_FREQUENCY_CL1	1	5 or more times a week
	2	2-4 times a week
	3	Once a week
	4	1-3 times a month
	5	Less than once a month
	6	Never
	-1	Refused
	-2	Don't Know
ALCOHOL_FREQUENCY_CL2	-4	Missing in Error
	1	Never
	2	About once a month
	3	About once a week
	4	About once a day
	-1	Refused
	-2	Don't Know
	-3	Legitimate Skip
ALCOHOL_FREQUENCY_CL3	-4	Missing in Error
	1	5 or more times a week
	2	2-4 times a week
	3	Once a week
	4	1-3 times a month
	5	Less than once a month
	6	Never
	-1	Refused
ALCOHOL_FREQUENCY_CL4	-2	Don't Know
	-3	Legitimate Skip
	-4	Missing in Error
	1	Never
	2	About once a month
	3	About once a week
	4	About once a day
	5	Less than once a month
-1	Refused	
-2	Don't Know	
-3	Legitimate Skip	
-4	Missing in Error	

Need a master code list for a given domain and then indicate for a given item/response what the allowed values are.

# MDES comments

- Instruments and items are now versioned and with the exception of inconsistencies and inaccuracies are sufficient for current use
- Constraints need consistency, more structure, and associated metadata
- Skip patterns are not well coded (not in the instruments either)
- Code lists need refinement in representation

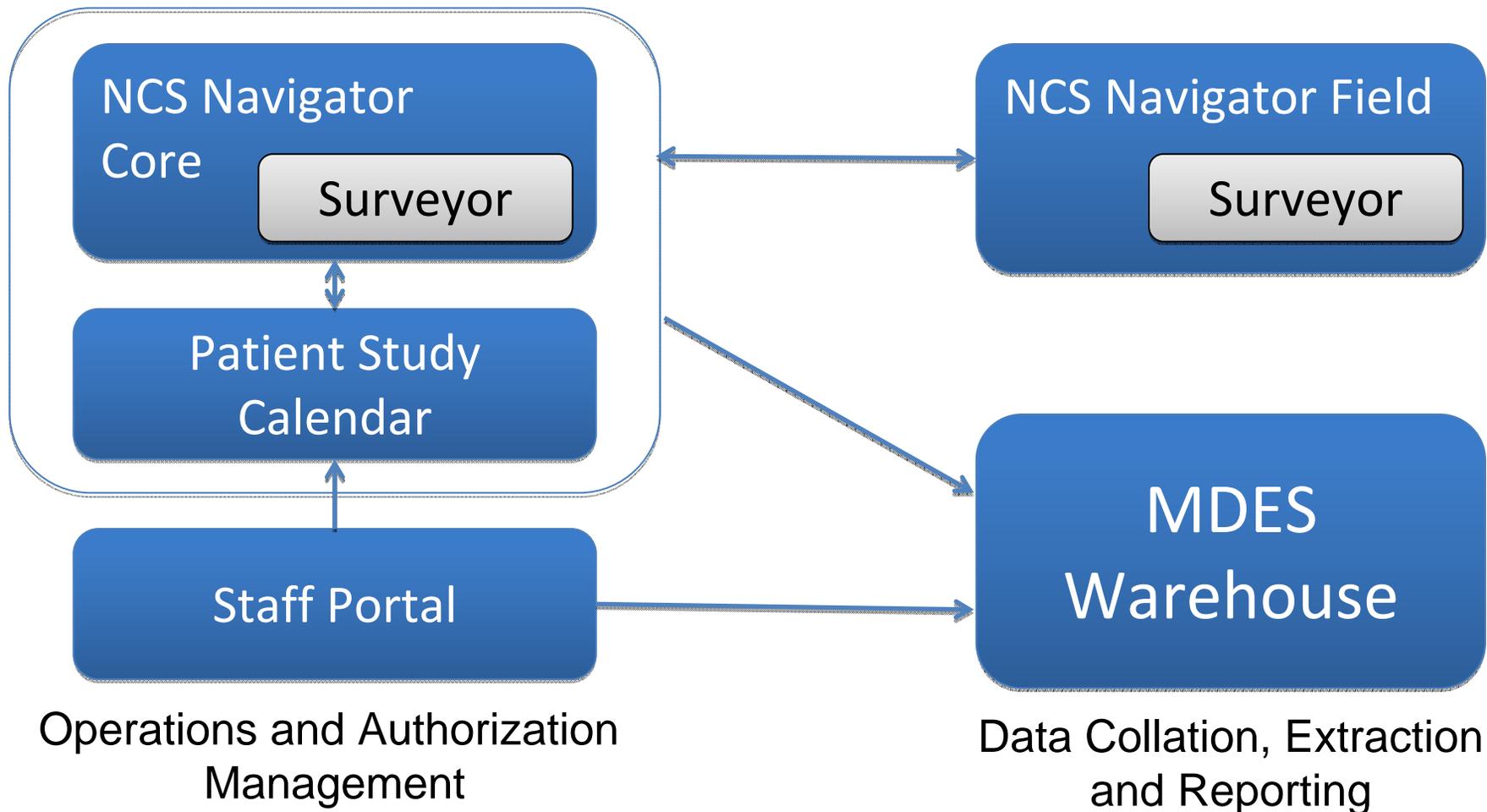
# NCS Navigator

- Making use of the MDES and instruments in an IMS
- MDES available as a set of Excel docs
- Instruments are available as Word docs

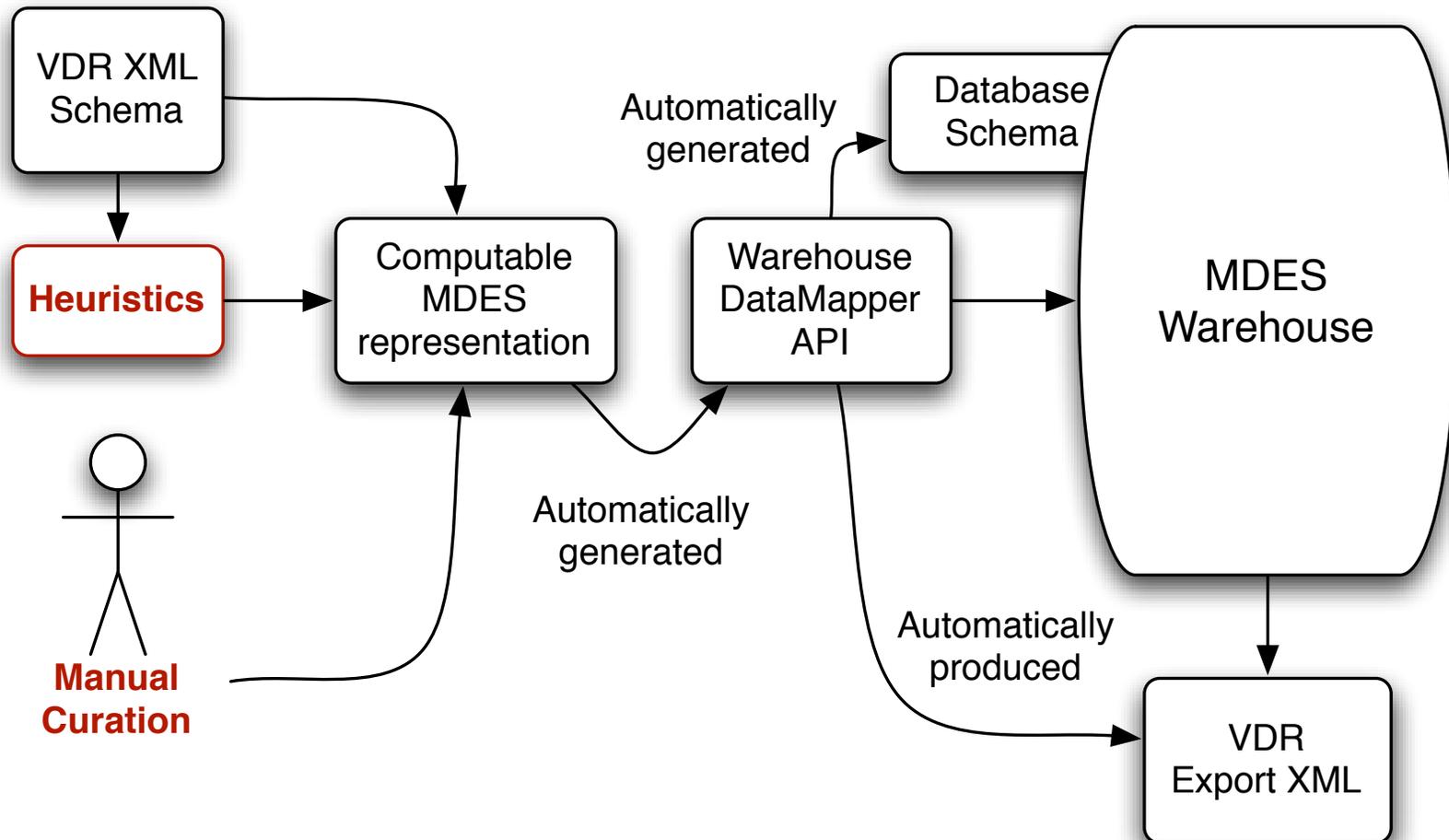
# NCS Navigator Modules

Online Data Collection  
and Case Management

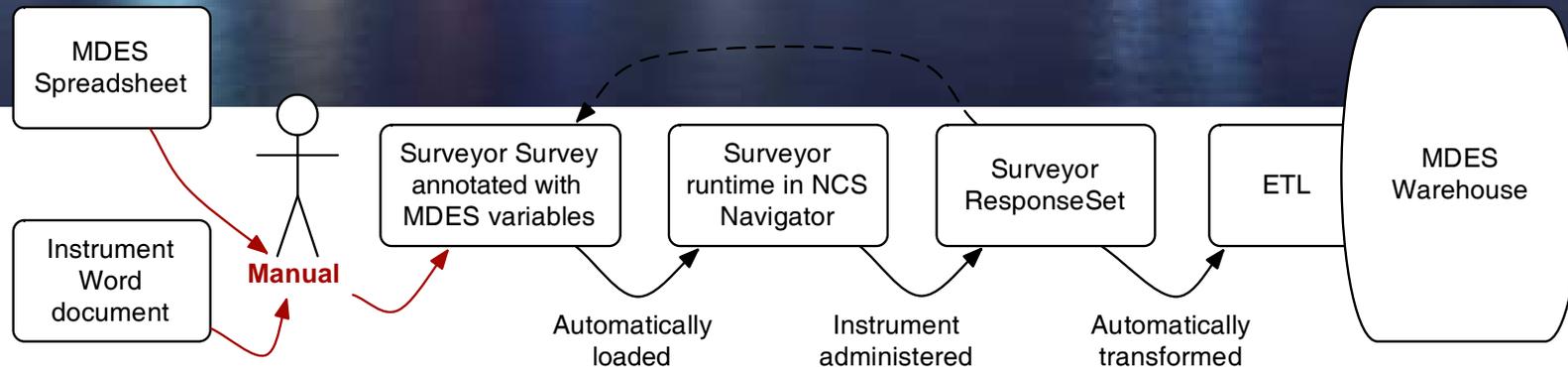
Offline Data Collection  
and Case Management



# MDES Warehouse and VDR



# NCS instruments



CPI012/(PREG\_VITAMIN). Since you've become pregnant, have you regularly taken multivitamins, prenatal vitamins, folate, or folic acid?

YES..... 1  
NO..... 2  
REFUSED..... -1  
DON'T KNOW..... -2

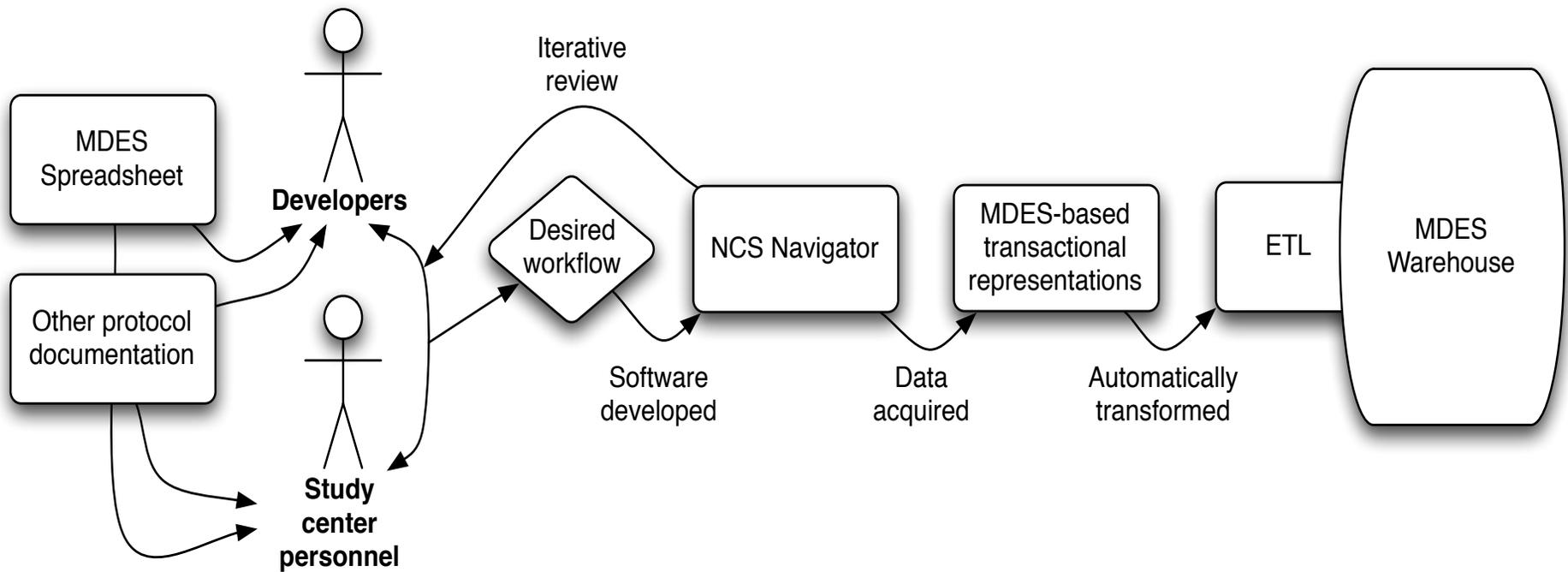


**× 3200**  
Questions in NCS  
Navigator for MDES 2.0

Plus we must manually interpret skip patterns, determine data to pre-fill, etc.

```
q_preg_vitamin "Since you've become pregnant, have you regularly taken
multivitamins, prenatal vitamins, folate, or folic acid?",
:pick=>:one,
:data_export_identifer=>"PREG_VISIT_1_2.PREG_VITAMIN"
a_1 "Yes"
a_2 "No"
a_neg_1 "Refused"
a_neg_2 "Don't know"
```

# MDES Warehouse loading



# Lessons from caBIG

- Semantics
- Harmonization
- Domain models
- Versioning

The features of PSC generally support three basic functions:

- Create a template to represent the activities of a study protocol
- Assign the appropriate parts of the template to a subject with start dates to generate a calendar
- Manage changes to the schedule and state of activities as the subject progresses through the study



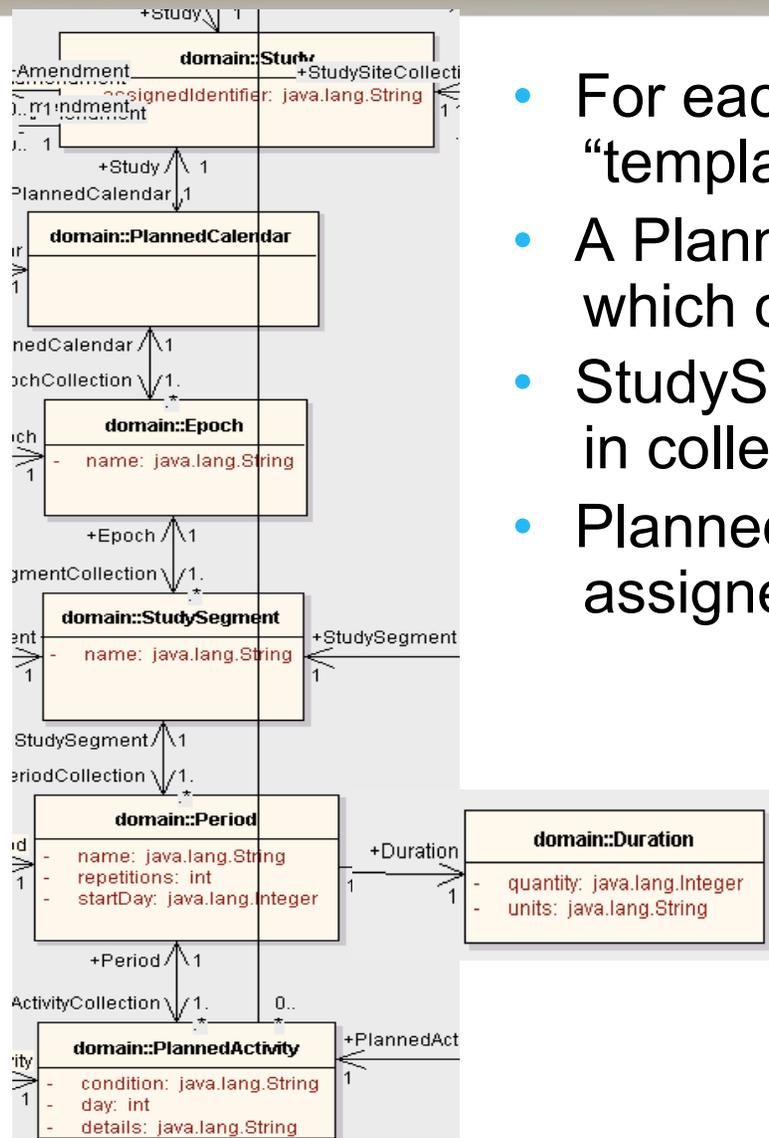
# PSC model walkthrough



We will examine the model in logical sections:

- **Planned**
- **Amendments**
- **Scheduled**
- **General clinical trials classes**

# PSC Planned



- For each study, a PlannedCalendar (called a “template” in the UI) is created.
- A PlannedCalendar has one or more Epochs, which contain one or more StudySegments.
- StudySegments have periods, which define time in collections of days that may repeat
- PlannedActivities are activities which have been assigned to happen on a day within a period

# PSC Planned in the UI

Epochs and study segments

Treatment	Follow up
Regimen A	Short term
Regimen B	Long term

Treatment: Regimen A

Hide All

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Cycle	x	x	x	x	x	x	x	x	x	x																		
	-	-	-	-	-	-	-	-	-	-																		

Day 1 Azacitidine (Subcutaneously once daily)  
CBC

Day 2 Azacitidine (Subcutaneously once daily)

Day 3 Azacitidine (Subcutaneously once daily)

- Here the Treatment and Follow up epochs each have two study segments.
- The study segment Regimen A is showing in the details box. It has a 28-day period (here named "Cycle") with activities on the first 10 days.

It is important to keep the end representation in mind (paper, telephone, eCRF, etc) during the design and harmonization process

# Lessons from caBIG

- Harmonization with the CDISC SDTM
- Harmonization itself does not guarantee semantic consistency
- caDSR has 404 terms matching “adverse event grade”
- Schemas, data elements and code lists need clear versioning and annotation with ‘current preferred term’

# Open Biomedical Ontologies

Gene Ontology (GO) is the quintessential OBO Ontology

- DAG
- Standard semantics
- Orthogonal ontologies
- Unique namespace
- Logical definitions
- Concept IDs
- External references
- Multiple relationships
- Atomically versioned



# The Disease Ontology

Harmonizing disease nomenclature and providing cross-mapping

**Warren Kibbe & Lynn Schriml**



Northwestern University University of Maryland  
School of Medicine



Warren A. Kibbe, Ph.D.  
Northwestern University  
[wakibbe@northwestern.edu](mailto:wakibbe@northwestern.edu)  
312-503-3229



# DO relationships

- We started with IS\_A
- We now have
  - Located\_in
  - Composed\_of
  - Part\_of
  - Occurs\_with
  - Results\_in
  - Transmitted\_by
  - Derives\_from

# Recent Paper

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## Nucleic Acids Research

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### Nucleic Acids Research

Increased Impact Factor of 7.836

### **Disease Ontology: a backbone for disease semantic integration**

[Lynn Marie Schriml](#)<sup>1,2,\*</sup>, [Cesar Arze](#)<sup>2</sup>, [Suvana Nadendla](#)<sup>2</sup>, [Yu-Wei Wayne Chang](#)<sup>1,2</sup>, [Mark Mazaitis](#)<sup>2</sup>, [Victor Felix](#)<sup>2</sup>, [Gang Feng](#)<sup>3</sup> and [Warren Alden Kibbe](#)<sup>3,\*</sup>

#### **This Article**

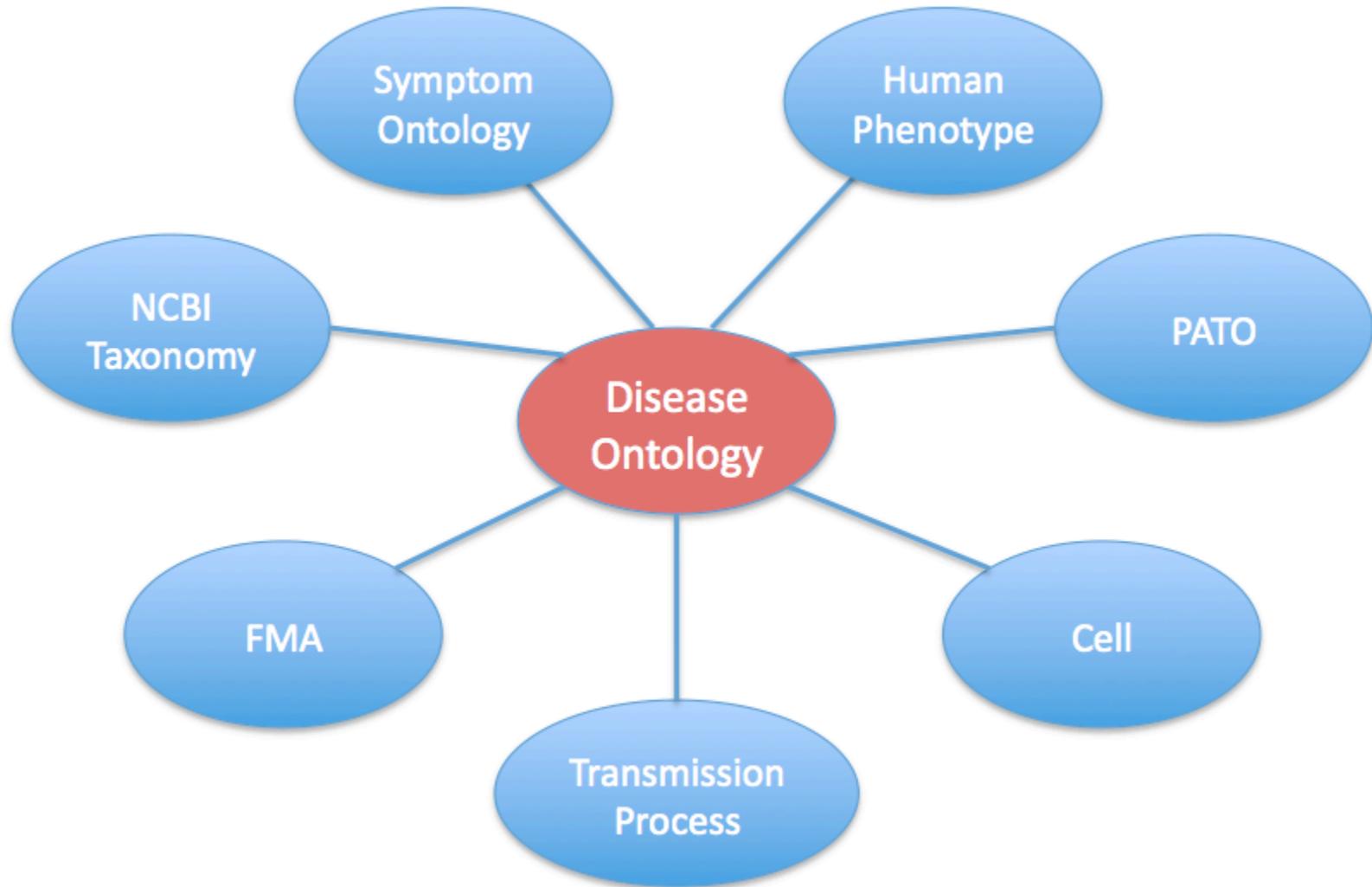
Nucl. Acids Res. (2011)  
doi: 10.1093/nar/gkr972  
First published online: November 12, 2011

This article is Open Access

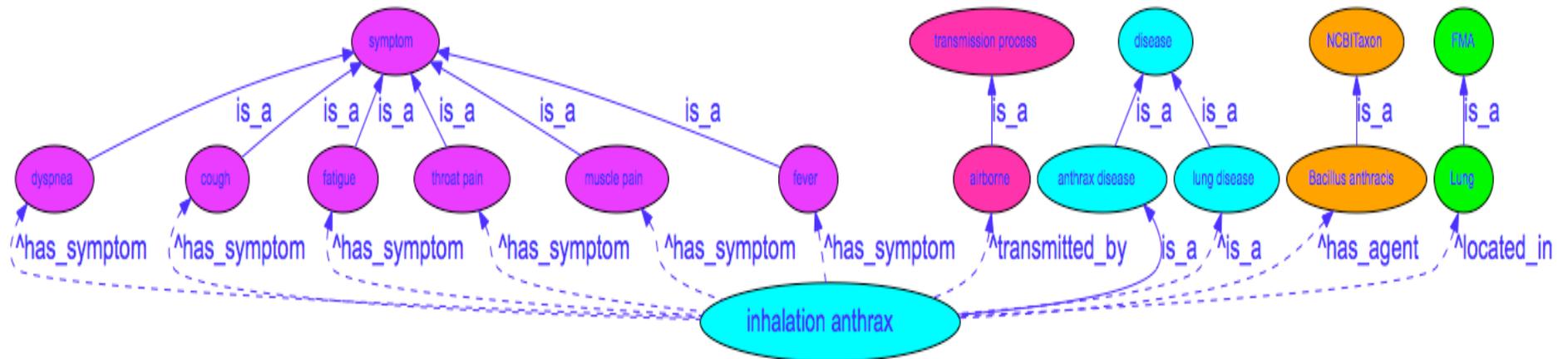
# Logical Definitions

- id: DOID:0050007
- name: cutaneous strongyloidiasis
- def: "A strongyloidiasis that involves parasitic infection by the filariform larvae of *Strongyloides stercoralis*, which penetrate the human skin causing urticarial rashes in the buttocks and waist areas." [url:<http://www.dpd.cdc.gov/dpdx/HTML/Strongyloidiasis.htm>]
- is\_a: DOID:10955 ! strongyloidiasis
- intersection\_of: DOID:10955 ! strongyloidiasis
- intersection\_of: has\_agent NCBITaxon:6248 ! *Strongyloides stercoralis*
- intersection\_of: located\_in FMA:7163 ! Skin

# Intersecting ontologies

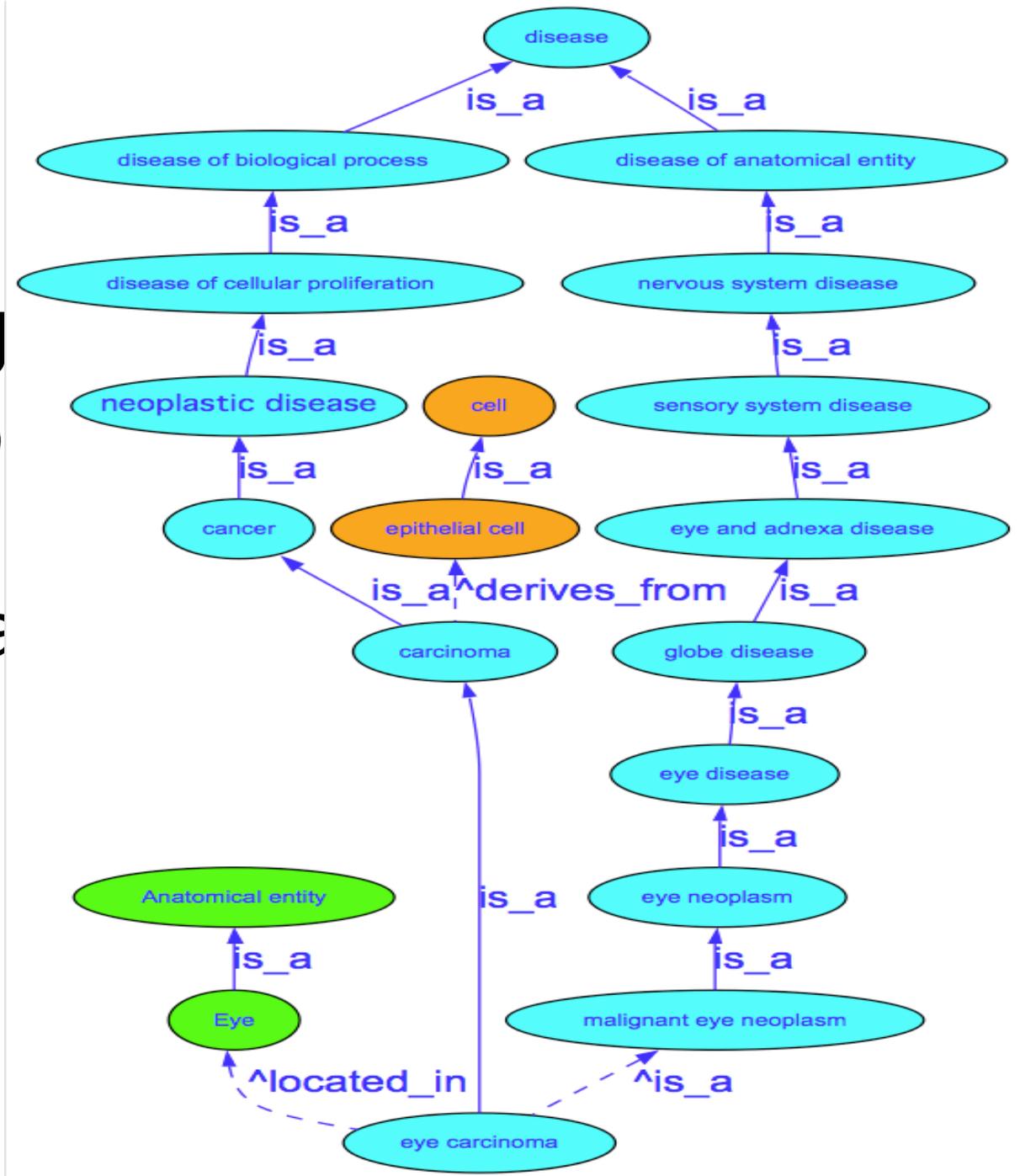


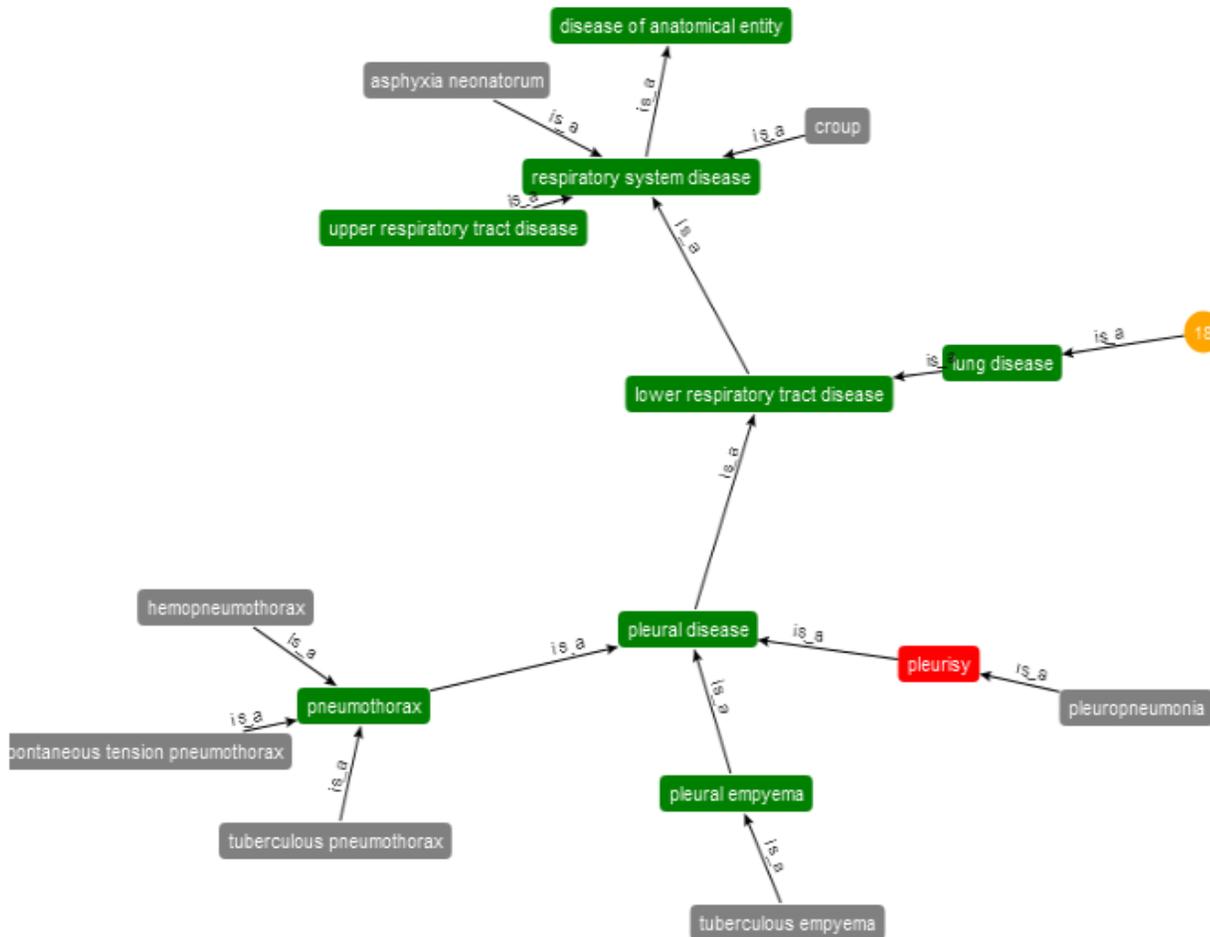
# Graph of Logical Definitions



Inhalation anthrax

DO Grap  
 showing  
 intersectio  
 (eye  
 carcinoma





Key

Visualization Key

Node Type	Description
disease	The target node of the visualization
cancer	A node which has children or parents. Can be clicked to display children/parents.
hyperuricemia	A leaf node
13	A node which has more than 5 children/parents is compacted to avoid cluttering the visualization space. This node can be clicked and one or many children/parents can be expanded out of it

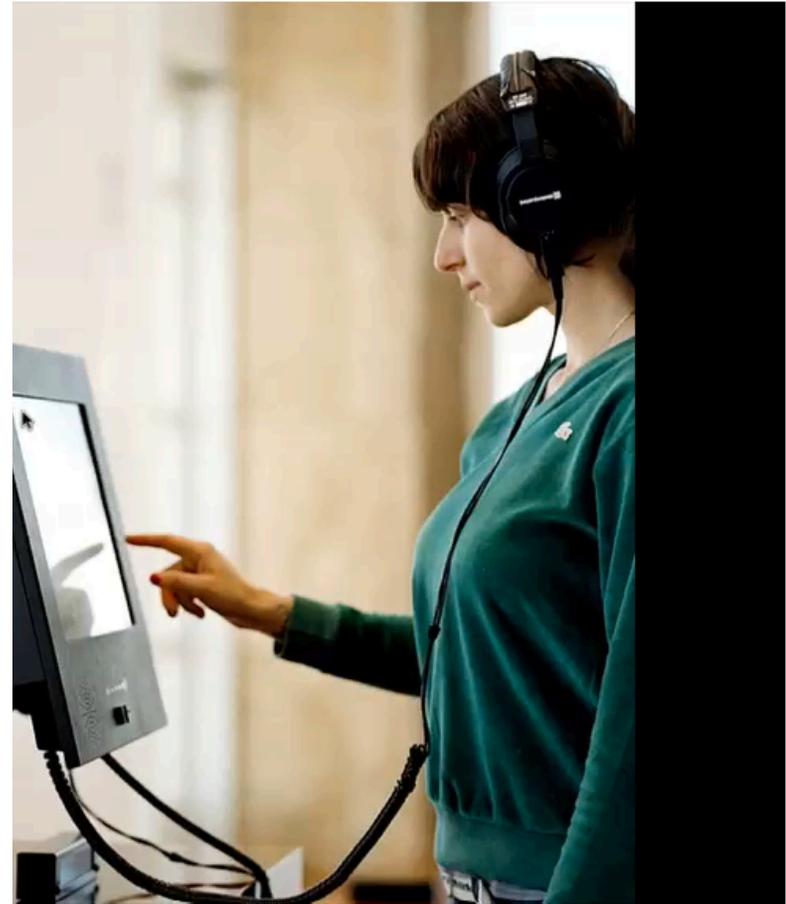
## Term Visualization in the Disease Ontology web-browser.

The 'Visualize' button on the Metadata page opens a graphical view of DO. Clicking on this button will open a new tab that will display the target node of the visualization (e.g. basidiobolomycosis) [red box], parent node [green box] and sibling leaf nodes [gray box]. Nodes with five or more children are represented by a gold circle containing the number of children. Clicking on a node in the graph will expand the view.



# NCS MDES and VDR

- Instruments, items, and data elements are now versioned
- Data element constraints need consistency, more structure, and associated metadata
- Skip patterns are not well coded in the MDES or in the instruments
- Code lists need refinement in representation and independence from the usage in a given instrument



*The NCS is playing a visionary role in the use of data standards, semantics. Practices that support the maintenance and longevity of the data elements and mappings between versions are critical*

# Recommendations

## Move docs to a publicly accessible repository (git or mercurial)

- Text files are good! Easy to version and operate on
- Need more structure and validation
- Use versioning tools
- Restrict write access
- Public access to all instruments and data elements
- Provide access to proposed changes and the change history through the same mechanism
- Use a ‘computable representation’ as the master version, all human readable docs should be derived through a reproducible process

---

# Thank You!

- Questions?

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# NCS Navigator Additional Features

- Provides research coordinator/field worker case load and load distribution feature
- Tracks participant flow, contacts and scheduling
- Provides sample tracking and tracing
- Scheduling is provided through the Patient Study Calendar, enabling new study designs to be configured and tested with minimal software changes .
- Sophisticated BI and Reporting through the semantically-aware MDES Warehouse

# Collaboration/code pages

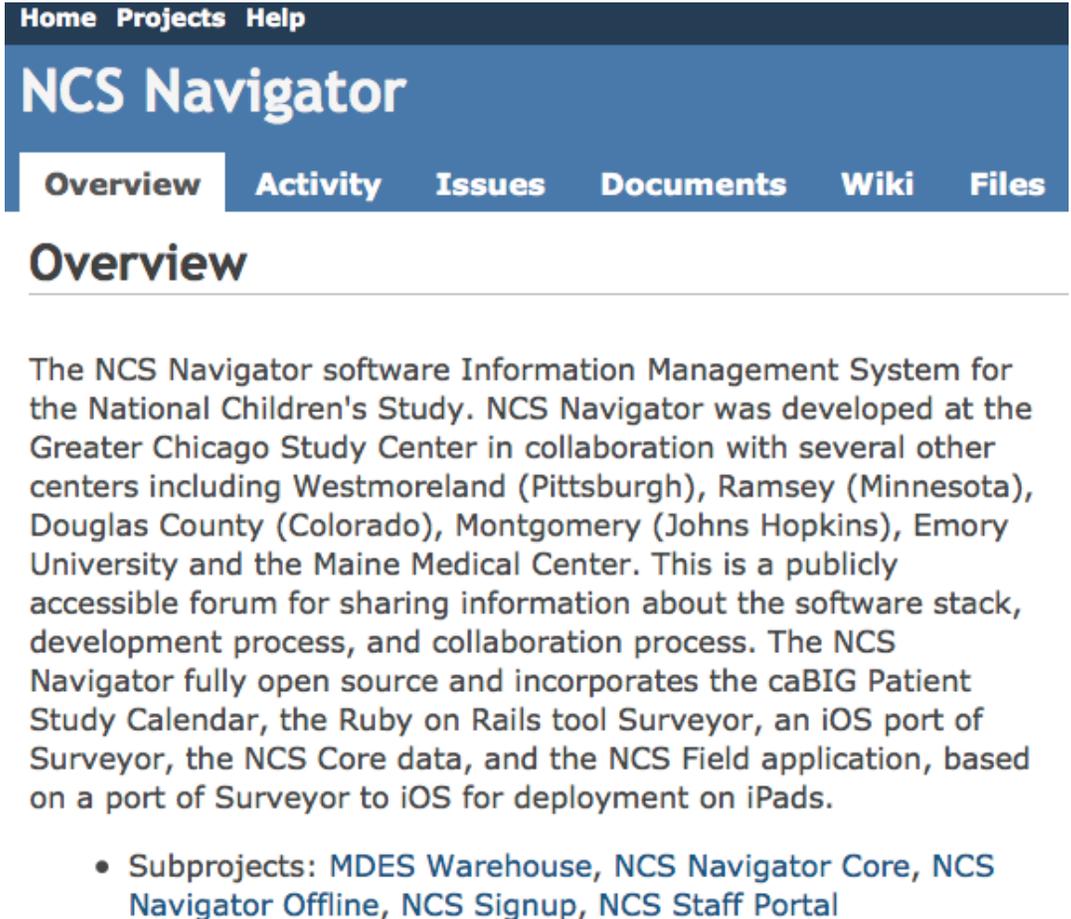
<https://code.bioinformatics.northwestern.edu/issues/wiki/ncs-navigator/>

<https://github.com/nubic>

NCS Navigator and components including the Patient Study Calendar, the NCS signup page (PII page), NCS Staff Portal, Surveyor and the MDES Warehouse are all accessible here

# NCS Navigator Tracker

Redmine provides an integrated wiki, code repository and tracker for the NCS Navigator. All activities are publicly accessible and provides a forum for public comments as well as feature and bug tracking.



The screenshot shows the NCS Navigator web application interface. At the top, there is a navigation bar with links for "Home", "Projects", and "Help". Below this is a large blue header with the text "NCS Navigator". Underneath the header is a secondary navigation bar with tabs for "Overview", "Activity", "Issues", "Documents", "Wiki", and "Files". The "Overview" tab is currently selected. Below the navigation bars, the word "Overview" is displayed in a large, bold font. The main content area contains a paragraph of text describing the NCS Navigator software Information Management System for the National Children's Study. It mentions that the system was developed at the Greater Chicago Study Center in collaboration with several other centers, including Westmoreland (Pittsburgh), Ramsey (Minnesota), Douglas County (Colorado), Montgomery (Johns Hopkins), Emory University, and the Maine Medical Center. The text states that this is a publicly accessible forum for sharing information about the software stack, development process, and collaboration process. It also mentions that the NCS Navigator is fully open source and incorporates the caBIG Patient Study Calendar, the Ruby on Rails tool Surveyor, an iOS port of Surveyor, the NCS Core data, and the NCS Field application, based on a port of Surveyor to iOS for deployment on iPads. At the bottom of the screenshot, there is a bulleted list of subprojects: MDES Warehouse, NCS Navigator Core, NCS Navigator Offline, NCS Signup, and NCS Staff Portal.

Home Projects Help

## NCS Navigator

Overview Activity Issues Documents Wiki Files

### Overview

The NCS Navigator software Information Management System for the National Children's Study. NCS Navigator was developed at the Greater Chicago Study Center in collaboration with several other centers including Westmoreland (Pittsburgh), Ramsey (Minnesota), Douglas County (Colorado), Montgomery (Johns Hopkins), Emory University and the Maine Medical Center. This is a publicly accessible forum for sharing information about the software stack, development process, and collaboration process. The NCS Navigator fully open source and incorporates the caBIG Patient Study Calendar, the Ruby on Rails tool Surveyor, an iOS port of Surveyor, the NCS Core data, and the NCS Field application, based on a port of Surveyor to iOS for deployment on iPads.

- Subprojects: MDES Warehouse, NCS Navigator Core, NCS Navigator Offline, NCS Signup, NCS Staff Portal

# NCS Navigator Wiki

<https://code.bioinformatics.northwestern.edu/issues/wiki/ncs-navigator>

Home Projects Help Sign in

## NCS Navigator

Search:

Overview Activity Issues Documents **Wiki** Files

### NCS Navigator Development wiki ← History

- Questions
- Core Requirements
- Adopter List
- Adopter Documentation
- Demos
- Timeline
- User Roles
- Notes on NCS Tools
  - **VDR Submission**
  - User Validation Tool for VDR Submission

Wiki

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Index by title  
Index by date

Also available in: HTML | TXT

# NCS Navigator demos

<https://code.bioinformatics.northwestern.edu/issues/wiki/ncs-navigator/Demos>

## NCS Navigator

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### Demos

◀ History

**Wiki**

Start page  
Index by title  
Index by date

**URLs:**

NCS Navigator Core: <https://navigator-demo.greaterchicagoncs.org> (main application entrance)  
NCS Signup Page: <https://signup-demo.greaterchicagoncs.org> (standalone public-facing site)  
NCS Staff Portal: <https://staffportal-demo.greaterchicagoncs.org> (staff information and access control)  
NCS PSC: <https://navcal-demo.greaterchicagoncs.org> (study-calendar)

**Demo User Credentials:**

- username = ncsdemo-staff & password = ekibeulb

Please send feedback and comments to the NCS listservs ([NCS-NAVIGATOR@LISTSERV.IT.NORTHWESTERN.EDU](mailto:NCS-NAVIGATOR@LISTSERV.IT.NORTHWESTERN.EDU)).