

Epoch Ontological Framework to support Clinical Trial Management

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Overview

- Clinical trials are used to determine whether new drugs or treatments are both safe and effective.
- Complex clinical trials involve collaboration among many groups using different software applications.
- Lack of standardization and reduced efficiency leads to poor productivity.
- We are building an ontological framework called **Epoch** to improve semantic interoperability among clinical trial management applications.

The Immune Tolerance Network

- ITN is an international collaboration designed to accelerate the development of immune tolerance therapies
- Funds, plans, implements, monitors, and assesses investigator-initiated clinical trials of novel tolerance-promoting therapies in
 - Autoimmune diseases
 - Transplantation
 - Allergy and Asthma
- Provides services to undertake comprehensive mechanistic studies that complement each trial

Schedule of Events

Table 7: Summary of Assessments for Subjects

	Screening Pre-MS Review Panel	Screening Post-MS Review Panel	Baseline	Post-mobilization & Pre-conditioning	Day 0 (Transplant)	Day +1 to +28	Week 4 (Month 1)	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30	Month 36	Month 42	Month 48	Month 54	Month 60
Visits	SC1	SC2	-1	PM	0	1 ^a	2	3	4	5	6	7	8	9 ^b				
Informed Consent																		
Signed Screening Informed Consent	X																	
			X															
	X																	
	X								X	X	X	X	X	X	X	X	X	X
	X		X	X					X	X	X	X	X	X	X	X	X	X
			X						X	X	X	X	X	X	X	X	X	X
			X						X	X	X	X	X	X	X	X	X	X
Medical History and Physical Exam																		
Medical History	X																	
Physical Exam and Health Assessments ^d	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Post-Mobilization or Post-Transplant Acute Toxicity Assessment				X			X	X	X									
Clinical Procedures & Assessments																		
CBC with differential and platelets		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

^aClinical

week until Day 28 or discharge from hospital (see MOP).

^bThe 60-month visit is the study primary endpoint evaluation visit. Subjects who meet the primary endpoint (Section 3.2.1) should undergo a complete end of study evaluation (see Section 6.3.7.2), and will, in addition, continue to be followed on the schedule listed in Section 6.3.7.1. Study subjects withdrawn from the trial for any reason prior to the 60-month evaluation should undergo a complete end of study evaluation if possible (see Section 6.3.7.2).

Schedule of Events

Period

Temporal
Constraint

Summary of Assessments for Subjects

	Screening Pre-MS Review Panel	Screening Post-MS Review Panel	Baseline	Post-mobilization & Pre-conditioning	Day 0 (Transplant)	Day +1 to +28	Week 4 (Day 28)	Day 56						
Visits	SC1	SC2	-1	PM	0									
Informed Consent														
Signed Screening Informed Consent	X													
Signed Treatment Informed Consent														
	X													
	X								X	X	X	X	X	X
	X		X	X					X	X	X	X	X	X
			X						X	X	X	X	X	X
			X						X	X	X	X	X	X
Exam														
Medical History	X													
Physical Exam and Health Assessments ^d	X		X	X	X	X	X	X	X	X	X	X	X	X
Post-Mobilization or Post-Transplant Acute Toxicity Assessment				X			X	X	X					
Clinical Procedures & Assessments														
CBC with diff and platelets		X	X					X	X	X	X	X	X	X

Visit

Time
Anchor

Activity

Annotation

^aClinical assessments are required twice a week until Day 0 or discharge from hospital (see MOP).

^bThe point evaluation visit and the Study Completion Visit. Subjects who meet the primary endpoint (see Section 6.3.7.2), and will, in addition, continue in Section 6.3.7.1. Study subjects withdrawn from the trial for any reason prior to the complete end of study evaluation at the time of meeting the primary endpoint will undergo a complete end of study evaluation if possible (see Section 6.3.7.2).

Specimen Table

	A	B	C	
1	Specimen Name	Collection Tubes	Blood/Specimen Volume	Processing/ Shipping
2	Serum-Archive	2 x 10 ml SST red/gray top	20 ml	Invert several times to mix. Allow to clot 30 min. Freeze < -70°C.
3	Whole Blood - Flow Cytometry Panel Stainin	1 x 10 ml glass Na Heparin (sodium heparin--green top)	10 ml	Invert to mix; leave at room temp. until shipment
4	Frozen PBMC-Archive	12 x 8 ml CPT (sodium citrate gel and density gradient medium)	60 ml	Process according to ITM SOP. aliquot into 10 cryovials
5	Leukaphereses WBC-Archive	2 x 10 9 MNC		into 8 cryovials
		Stabilization solution (RNA stabilization solution) provided by site (sample)		and freeze
				in cryovials
				and protect

Specimen Table

Mechanistic Study

Processing Instruction

Specimen Container

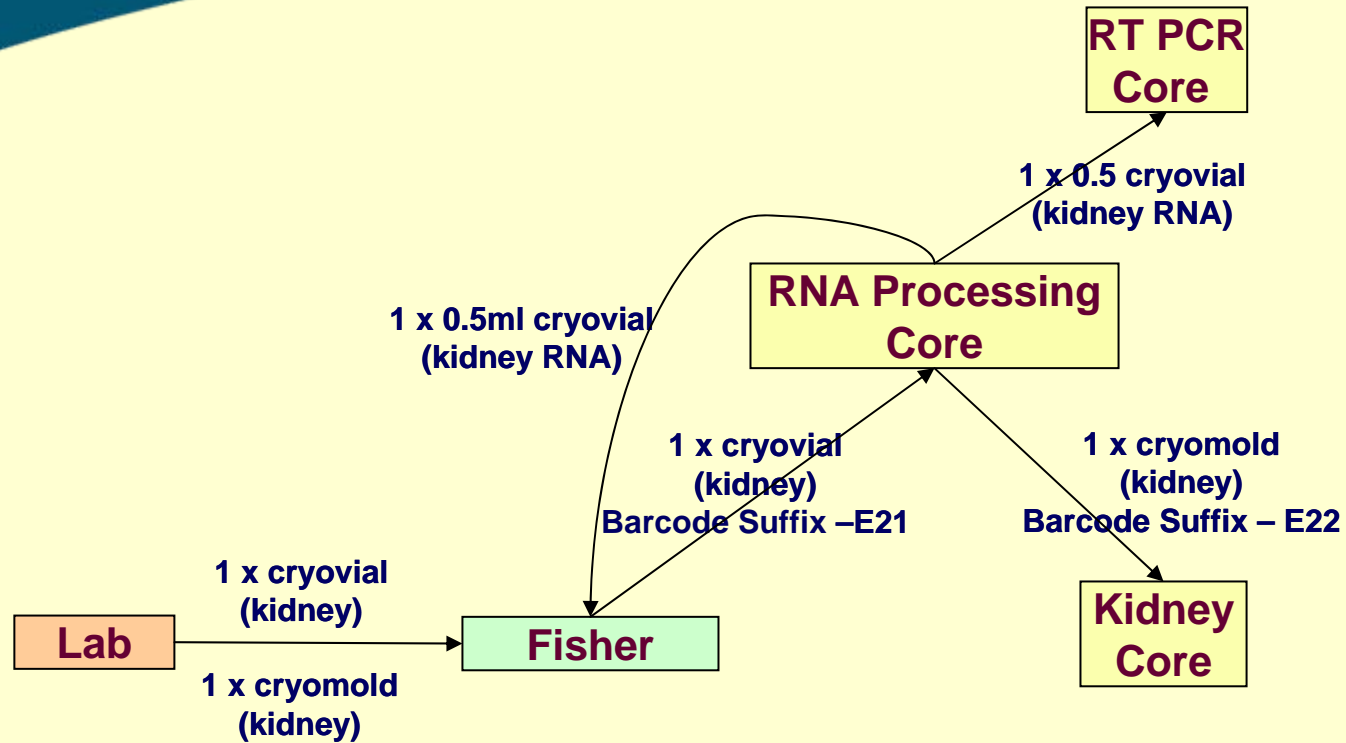
Specimen Workflow

Assay

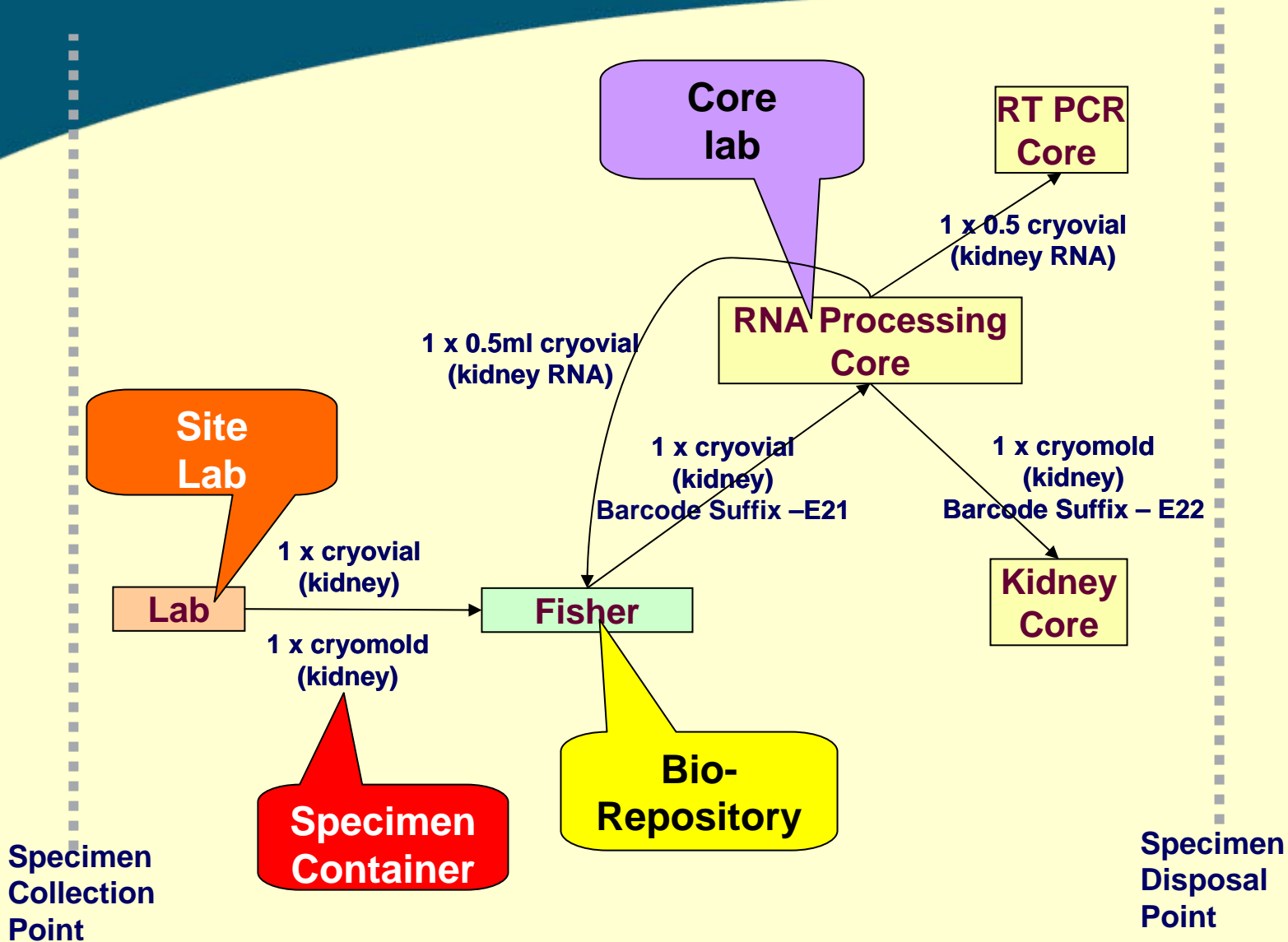
		B		C		Processing/Shipping	
		Collection Tubes		Blood/Specimen Volume		Processing/Shipping	
1	Serum-Archive	2 x 10 ml SST red/gray top		20 ml		Invert several times to mix. Allow to clot 30 min. Freeze <-70°C.	
2	Whole Blood - Flow Cytometry Panel Stain	1 x 10 ml glass Na Heparin (sodium heparin--green top)		10 ml		Invert to mix; leave at room temp. until shipment	
3	Frozen PBMC-Archive	12 x 8 ml CPT (sodium citrate gel and density gradient medium)		10 ml		Process immediately. ITACOP aliquot 10 cry	
4	Leukaphereses WBC-Archive	2 x 10.9 MMS				into 8	
		ous (RNA stabilization solution)				yd fre	
		es provided by site (sample:)				jovial	
						ucted	
		DTA lavender top tube		10 ml		DO NOT SPIN. aliquot equally into 10 x 1.8 ml c	
11	Shipping Instruction	Destination	Final Destination	Assay Instructions	Assay Details	Collection Time Points/Visits	Prior
12							
NOTE:	Dry Ice Mon - Wed only	Fisher	Fisher	Archive		-1,2,3,4,5,6,7,8,9	5
	Ship ambient within 24 hours	Flow C	Flow C	Flow Cytometry		4,5,6,7,8,9	2
	Dry Ice Mon-Wed only	Fis		Archive		4,5,6,	3
	Dry Ice Mon - Wed only	Fis				colle	5
	Dry Ice Mon - Wed only	Fis				4,5,6,	4
	Dry Ice Mon - Wed only	Fis				SC2, 6, 8 (
	Dry Ice Mon - Wed only	Fisher				relapse	
	Dry Ice Mon - Wed only	Fisher	Fisher	Archive		-1	6

previously met endpoint) reaches the 5-year end of study mark, they will have another end of study visit.

Specimen Workflow



Specimen Workflow



Challenges in Trials Management

- Knowledge about protocols, assays, and specimen flow is captured in documents and spreadsheets



Plan



Implement

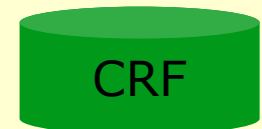
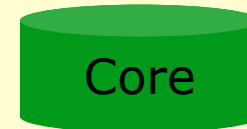


Monitor



Assess

The collage includes a table titled 'Plasma + Immunotherapy Plasma' with columns for 'Week' and 'Day'. It also shows a 'GENERAL ASSESSMENT & PROCEEDURES' section with various checkboxes and a 'Consent Form' with a signature line.



What is in a visit name?

Visit 0, v0, v 0, 0, Day 0, Transplant

Table 7: Summary of Assessments for Subjects

Visits	Screening Pre-MS Review Panel	Screening Post-MS Review Panel	Baseline	Post-mobilization & Pre-conditioning	Day 0 (Transplant)	Day +1 to +28	Week 4 (Day 28)	Week 6							
SC1	SC2	-1	PM	0	1 ^a	2	3	4	5	6	7	8	9 ^b		
Informed Consent															
Signed Screening Informed Consent	X														
			X												
	X														
	X							X	X	X	X	X	X		
	X		X	X				X	X	X	X	X	X		
			X					X	X	X	X	X	X		
			X					X	X	X	X	X	X		
Exam															
Medical History	X														
Physical Exam and Health Assessments ^d	X		X	X	X	X	X	X	X	X	X	X	X	X	
Post-Mobilization or Post-Transplant Acute Toxicity Assessment				X			X	X	X						
Clinical Procedures & Assessments															
CBC with diff and platelets		X	X	X	X	X	X	X	X	X	X	X	X	X	

^aClinical assessments are required twice a week until Day 28 or discharge from hospital (see MOP).

^bThe point evaluation visit and the Study Completion Visit. Subjects who meet the primary endpoint (see Section 6.3.7.2), and will, in addition, continue in Section 6.3.7.1. Study subjects withdrawn from the trial for any reason prior to the complete end of study evaluation if possible (see Section 6.3.7.2).

What is in a visit name?

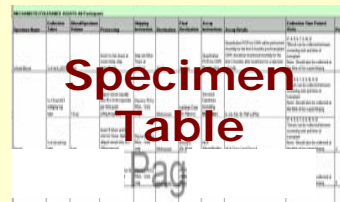
Visit 0, v0, v 0, 0, Day 0, Transplant

Protocol
Group 0

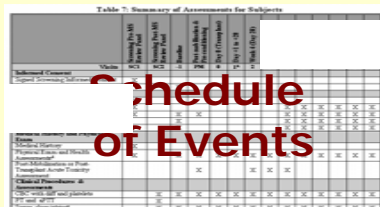
Assay
Group 0

Specimen
Table

Page



Schedule
of Events



What is in a visit name?

Visit 0, v0, v 0, 0, Day 0, Transplant

CRO Day 0, Transplant

A screenshot of a Clinical Research Form (CRF) titled "Day 0 Transplant". The form includes fields for "Patient ID", "Study ID", and "Visit". It also contains checkboxes for "Transplant" and "Transplant Date". The form is labeled "CRF" in large red letters.

Assay
Group 0

Protocol
Group 0

A screenshot of a "Specimen Table" showing columns for "Specimen ID", "Specimen Type", "Specimen Date", and "Specimen Status". The table contains several rows of data.

A screenshot of a "Schedule of Events" table showing columns for "Event", "Event Date", "Event Status", and "Event Description". The table contains several rows of data.

What is in a visit name?

Visit 0, v0, v 0, 0, Day 0, Transplant

CRO Day 0, Transplant

A screenshot of a Clinical Research Form (CRF) titled "Day 0 Transplant". The form includes fields for "Patient ID", "Study ID", and "Visit". It contains several checkboxes and text input fields for recording data related to the transplant procedure.

Assay
Group 0

Protocol
Group 0

A screenshot of a "Specimen Table" showing columns for "Specimen ID", "Specimen Type", "Specimen Source", "Specimen Date", "Specimen Time", and "Specimen Status". It contains multiple rows of specimen data.

Operations
Group v 0

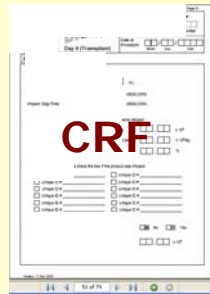
A screenshot of a "Tube Table" showing columns for "Tube ID", "Tube Type", "Tube Source", "Tube Date", "Tube Time", and "Tube Status". It contains multiple rows of tube data.

A screenshot of a "Schedule of Events" table showing columns for "Event ID", "Event Name", "Event Date", "Event Time", "Event Status", and "Event Description". It contains multiple rows of event data.

What is in a visit name?

Visit 0, v0, v 0, 0, Day 0, Transplant

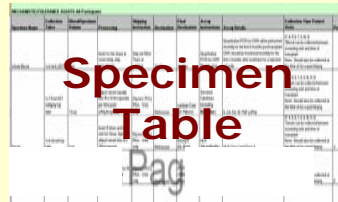
CRO Day 0, Transplant



CRF

**Assay
Group** 0

**Protocol
Group** 0



Specimen
Table

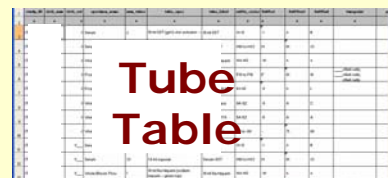
Fisher v 0



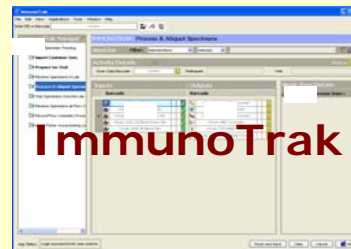
Kit
Report

**Operations
Group** v 0

Cimarron v0, Visit 0



Tube
Table



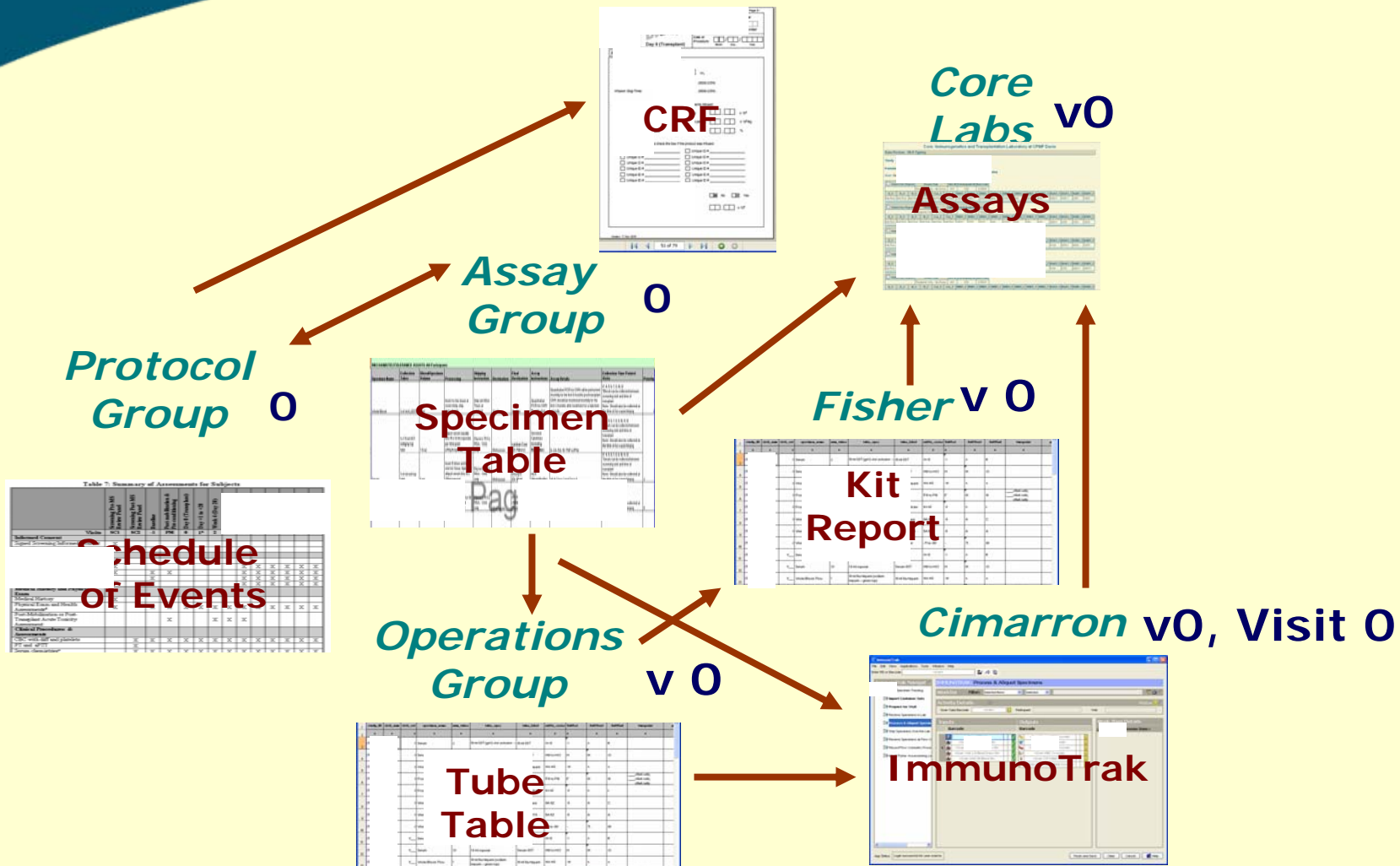
ImmunoTrak



Schedule
of Events

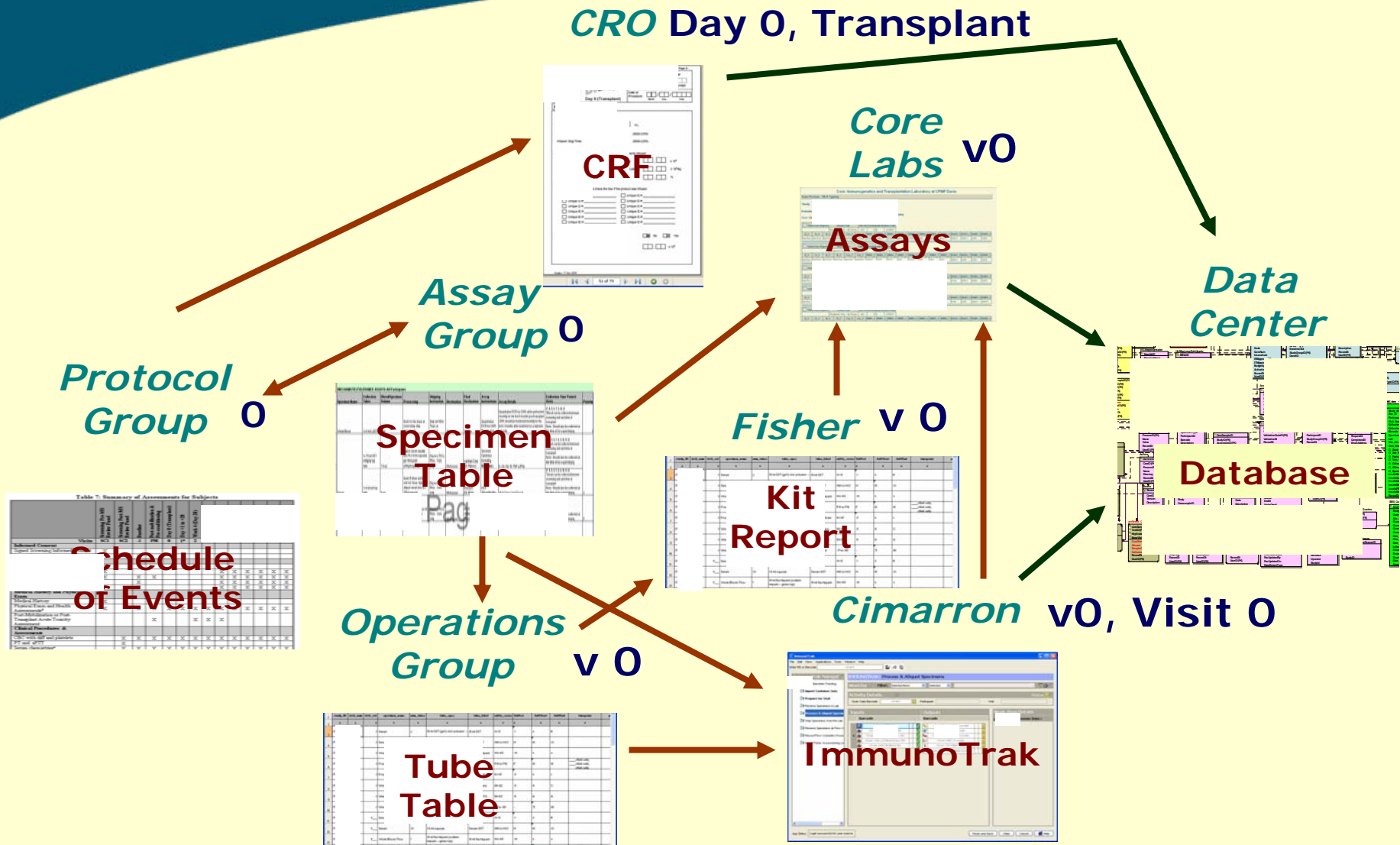
Visit 0, v0, v 0, 0, Day 0, Transplant

CRO Day 0, Transplant

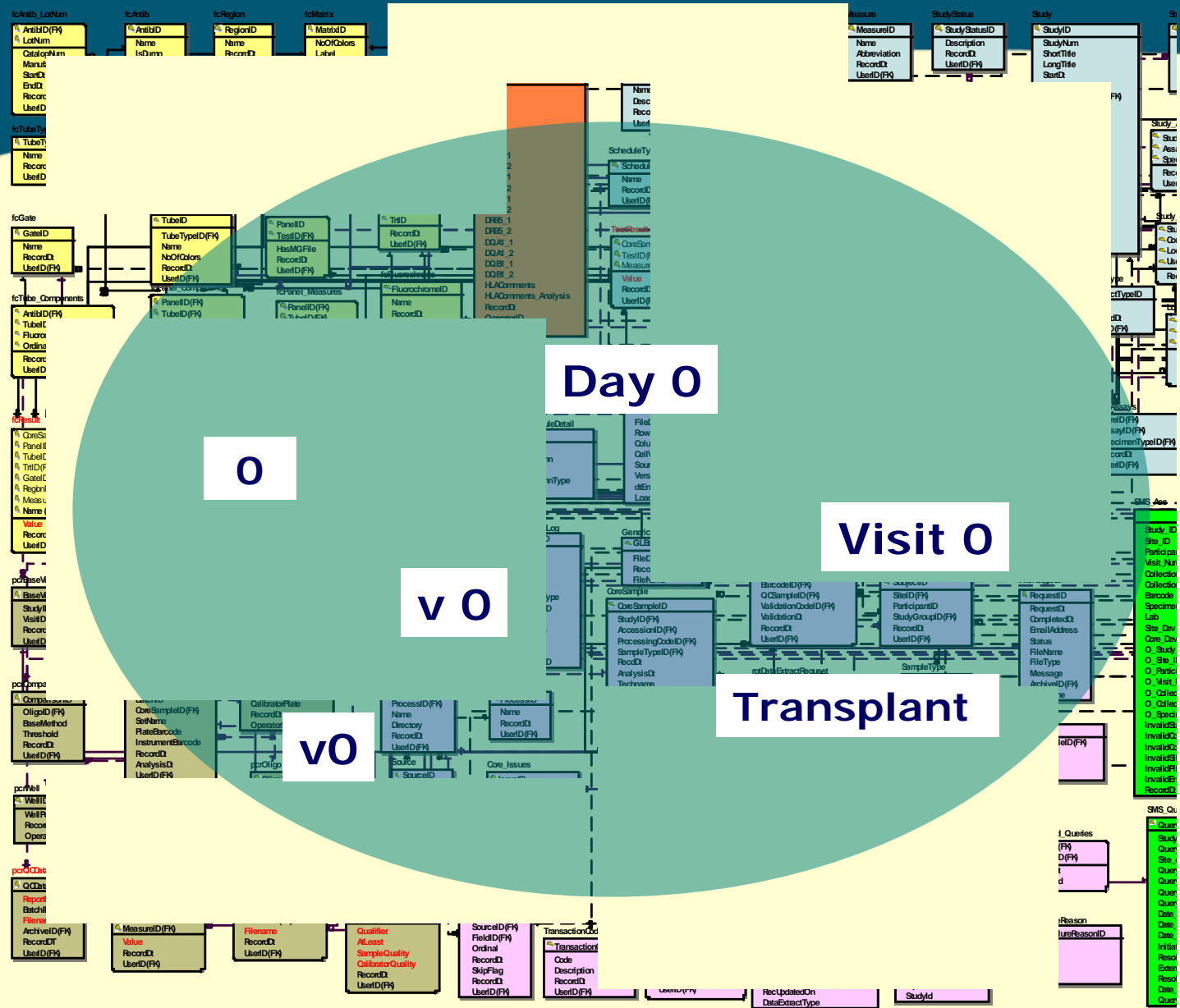


What is in a visit name?

Visit 0, v0, v 0, 0, Day 0, Transplant



What is in a visit name?



How many participants have had transplants so far and what are the results of the assays performed at the time of transplant?

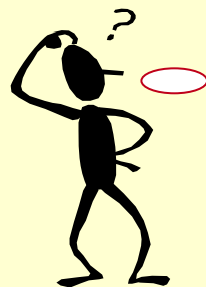
O

v 0

Visit 0

Transplant

v0



Challenges in Trials Management

- Enterprise-wide knowledge about trials management is not formally encoded, leading to challenges in
 - Standardization
 - Data integrity
 - Data analysis
 - Data integration
- Significant efforts may be needed to resolve inconsistencies after a trial has started

ITN Informatics Core at Stanford

Epoch

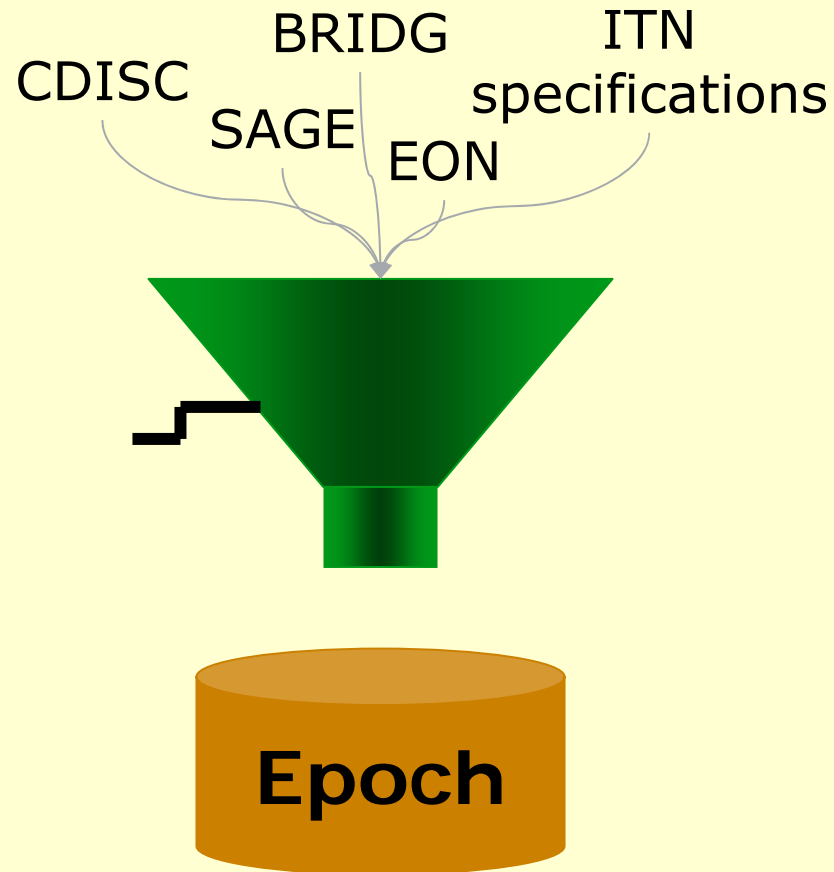
*An Ontological Framework for Clinical
Trials Management*

ITN Informatics Core at Stanford

The goals of our collaboration are to

- Design tools to help acquire and maintain knowledge about protocol and assay designs
- Use this knowledge to drive data collection during a trial
- Implement querying methods to support trial management, and ad hoc data analysis

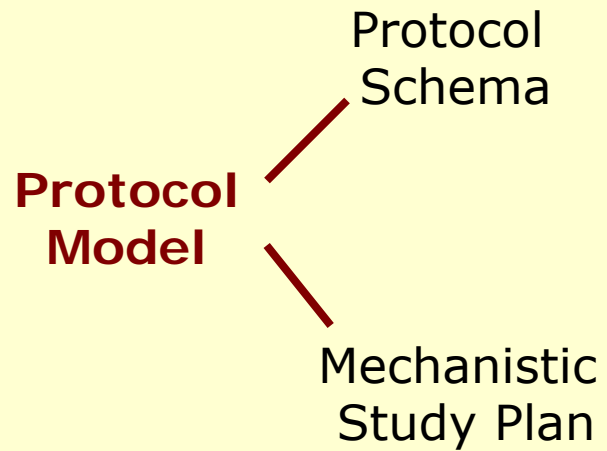
Building Ontologies for ITN — Epoch



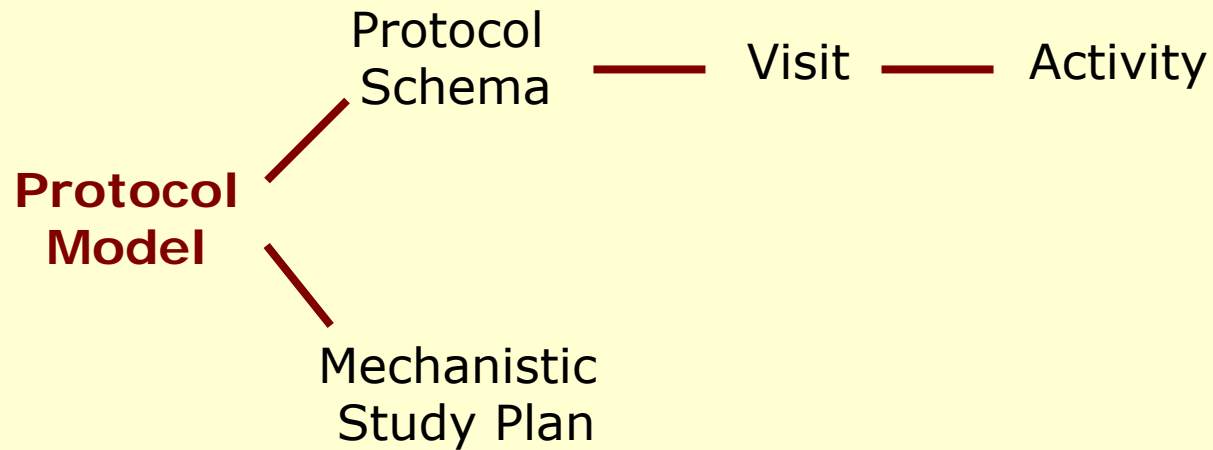
Epoch Ontologies

**Protocol
Model**

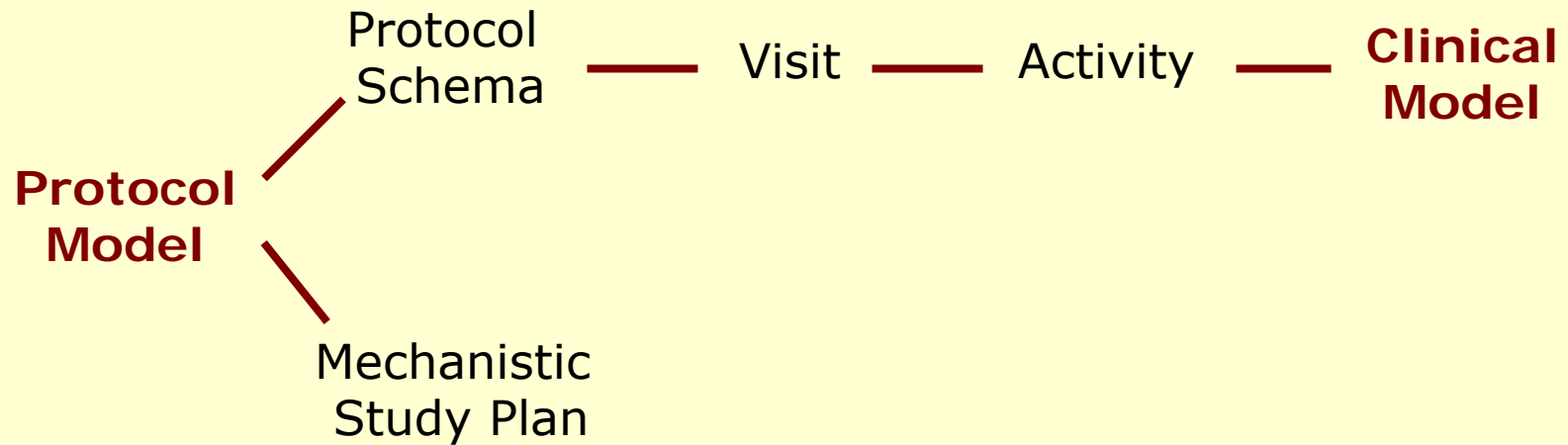
Epoch Ontologies



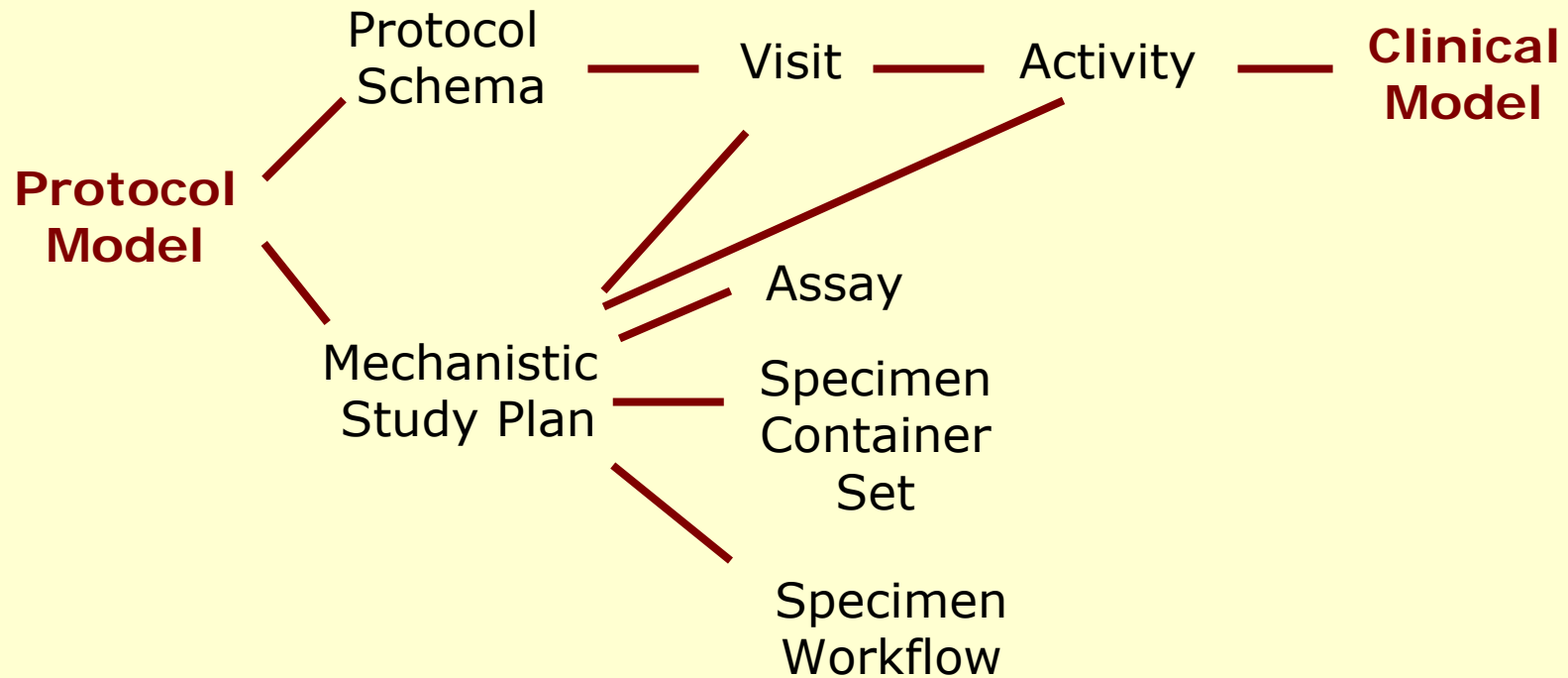
Epoch Ontologies



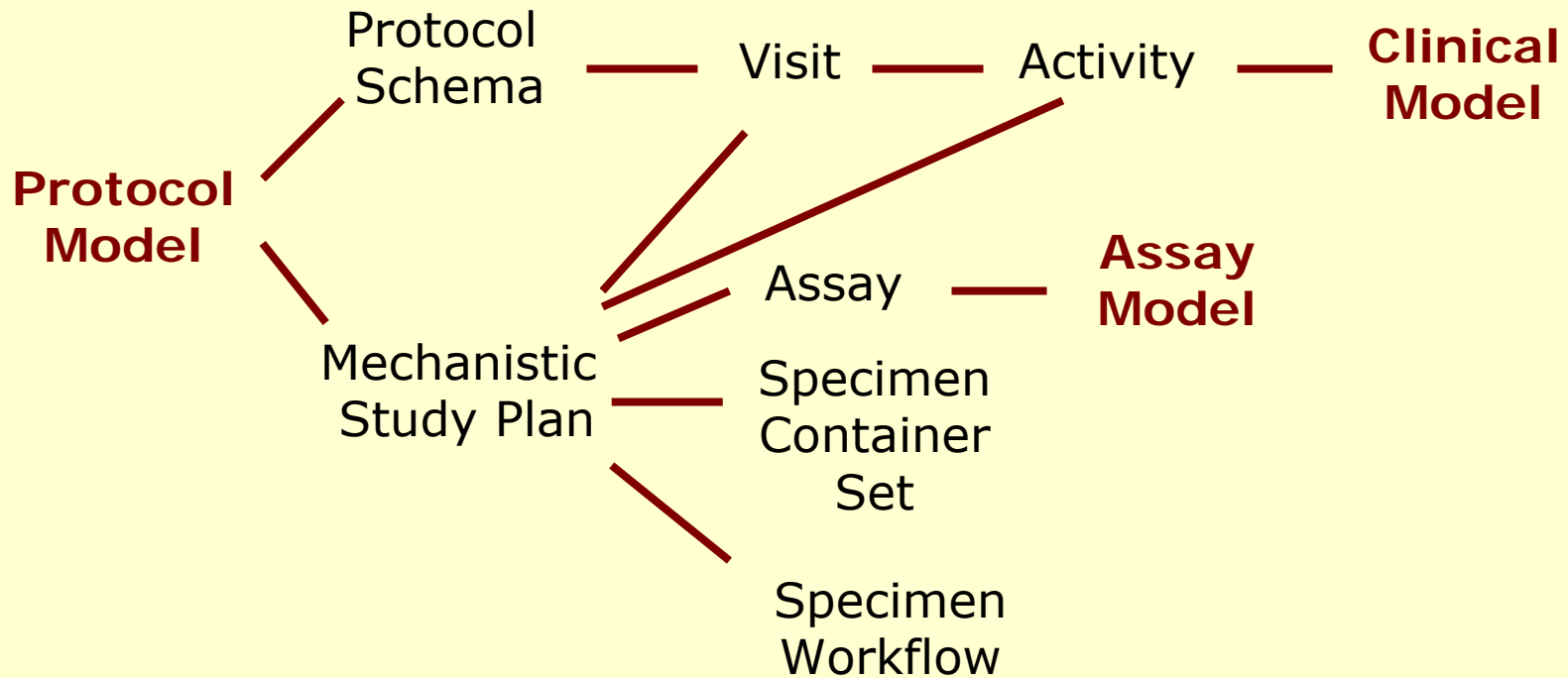
Epoch Ontologies



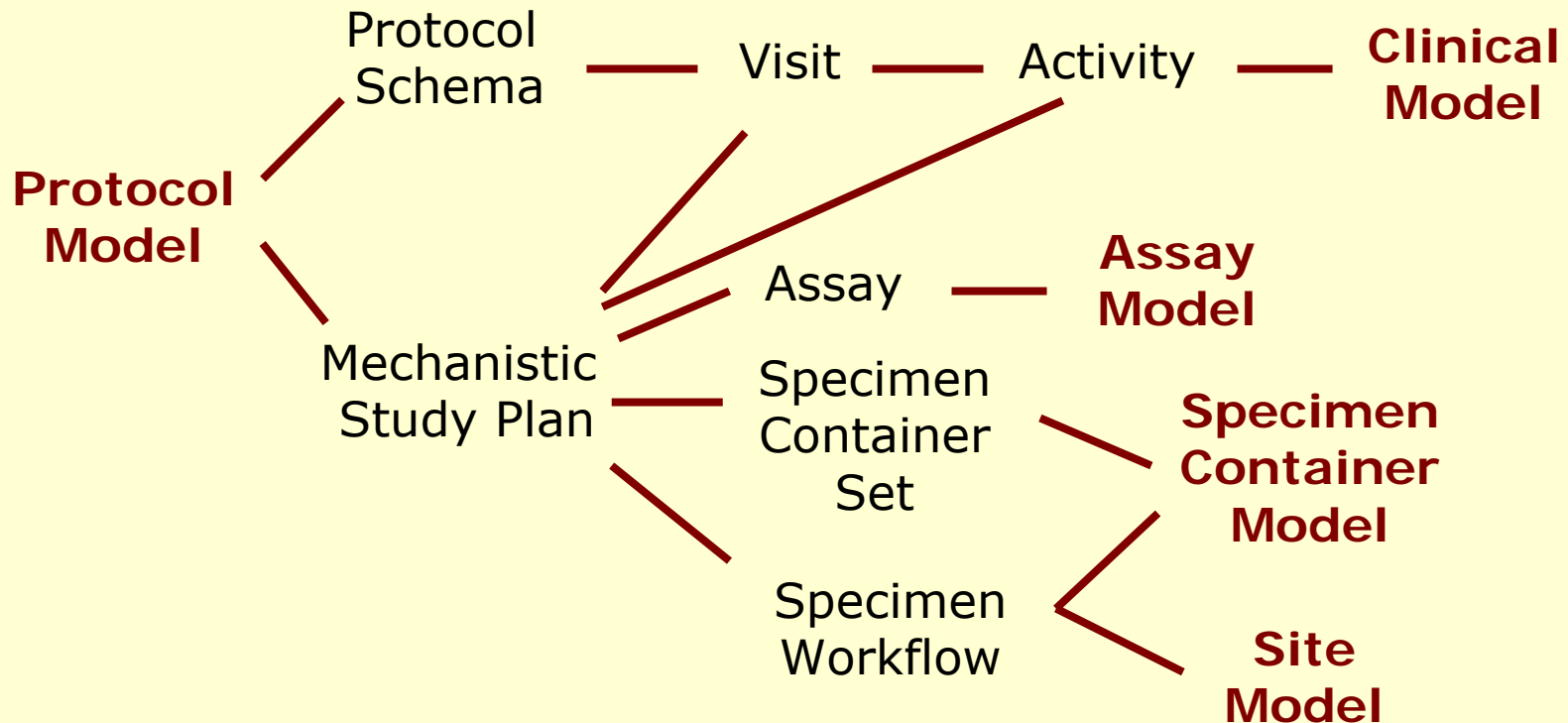
Epoch Ontologies



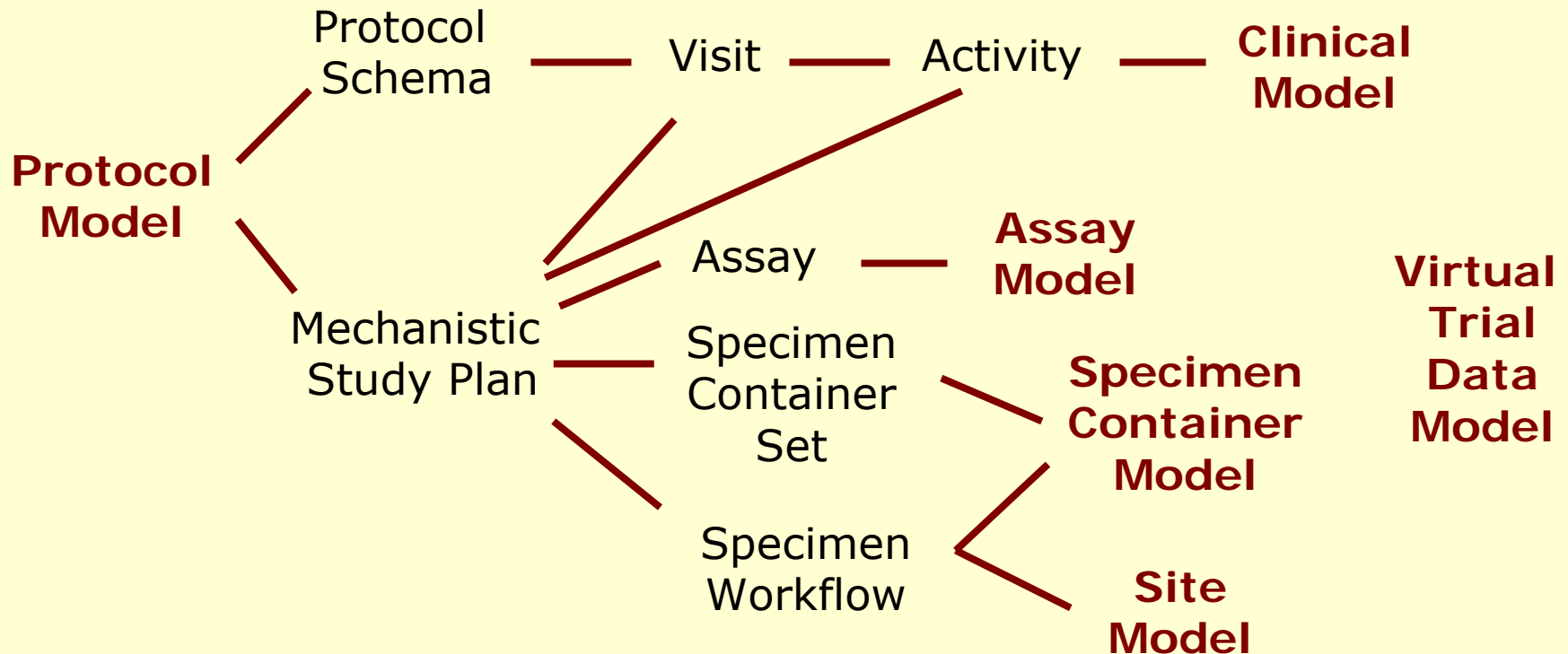
Epoch Ontologies



Epoch Ontologies



Epoch Ontologies



Knowledge-Acquisition Environment

OWL (the Web Ontology Language proposed by W3C)

SWRL (the Semantic Web Rule Language) to specify constraints and queries

Protégé-OWL editor to enter ontologies in OWL and SWRL

Epoch Protocol Model

EpochProtocolModel Protégé 3.2 beta (file: D:\Ravi\Projects\ITN\kb\Epoch\EpochProtocolModel.pprj, OWL / RDF Files)

File Edit Project OWL Code Tools Window Help

Metadata (EpochProtocolModel.owl) OWLClasses Properties Individuals Forms Knowledge Tree

SUBCLASS EXPLORER

For Project: EpochProtocolModel

Asserted Hierarchy

- org:PersonConcept
- org:SiteModelConcept
- scm:LabWare
 - scm:ProcessingRequirement
- scm:SpecimenType
- scm:StorageRequirement
- asy:Assay
- DataModel
- Expression
- ProtocolModelConcept
 - Protocol
 - SitePlanConcept
 - StudyInformation
 - StudyPlanConcept
 - MechanisticStudyConcept
 - ParticipantStatesConcept
 - StudyPlan
 - StudySchemaConcept
 - Arm
 - StudyPhase
 - StudySchemaDiagram
 - StudySchemaNode
 - StudySchemaTransition

CLASS EDITOR

For Class: StudyPlan (instance of owl:Class) ☐ Inferred View

Property	Value	Lang
rdfs:comment		

Properties and Restrictions

- hasArms (multiple Arm)
- hasMechanisticStudyPlan (single MechanisticStudyPlan)
- hasParticipantStateDiagram (single ParticipantStateDiagram)
- hasStudySchemaDiagram (single StudySchemaDiagram)

Superclasses

- StudyPlanConcept

Disjoints

Logic View Properties View

Epoch Protocol Model

ParticipantStateConcept

● StudyPlan

- hasArms (multiple Arm)
- hasMechanisticStudyPlan (single MechanisticStudyPlan)
- hasParticipantStateDiagram (single ParticipantStateDiagram)
- hasStudySchemaDiagram (single StudySchemaDiagram)

Schedule of Events

Period

Temporal
Constraint

Summary of Assessments for Subjects

	Screening Pre-MS Review Panel	Screening Post-MS Review Panel	Baseline	Post-mobilization & Pre-conditioning	Day 0 (Transplant)	Day +1 to +28	Week 4 (Day 28)	Day 56						
Visits	SC1	SC2	-1	PM	0									
Informed Consent														
Signed Screening Informed Consent	X													
Signed Treatment Informed Consent														
	X													
	X								X	X	X	X	X	X
	X		X	X					X	X	X	X	X	X
			X						X	X	X	X	X	X
			X						X	X	X	X	X	X
Exam														
Medical History	X													
Physical Exam and Health Assessments ^d	X		X	X	X	X	X	X	X	X	X	X	X	X
Post-Mobilization or Post-Transplant Acute Toxicity Assessment				X			X	X	X					
Clinical Procedures & Assessments														
CBC with diff and platelets		X	X					X	X	X	X	X	X	X

Visit

Time
Anchor

Activity

Annotation

^aClinical assessments are required twice a week until Day 0 or discharge from hospital (see MOP).

^bThe point evaluation visit and the Study Completion Visit. Subjects who meet the primary endpoint (see Section 6.3.7.2), and will, in addition, continue in Section 6.3.7.1. Study subjects withdrawn from the trial for any reason prior to the complete end of study evaluation at the time of meeting the primary endpoint will undergo a complete end of study evaluation if possible (see Section 6.3.7.2).

Protocol Model – Study Schema

- ▼ ● StudySchemaConcept
 - Arm
 - ▶ ● StudyPhase
 - StudySchemaDiagram
- ▼ ● StudySchemaNode
 - Period
 - StudySchemaTransition
 - TransitionRestriction
 - VisitFlow
- ▼ ● VisitFlowNode
 - Context
 - Decision
 - Visit
- VisitFlowTransition

Study Schema

File Edit Project OWL Code Tools Window Help

protégé

Metadata OWLClasses Properties Individuals Forms Knowledge Tree

Knowledge Tree

- epoch:hasStudyInformation
- epoch:hasSitePlan
- epoch:hasStudyPlan
 - epoch:hasMechanisticStudyPlan
 - epoch:hasStudySchemaDiagram
 - epoch:hasStudySchemaTransit
 - epoch:hasStudySchemaNodes
 - epoch:hasStartStudySchemaNode
 - Screening

INSTANCE EDITOR

For Instance: Schema (instance of epoch:StudySchemaDiagram, inter)

Property	Value
rdfs:comment	
rdfs:label	Schema

epoch:hasStartStudySchemaNode

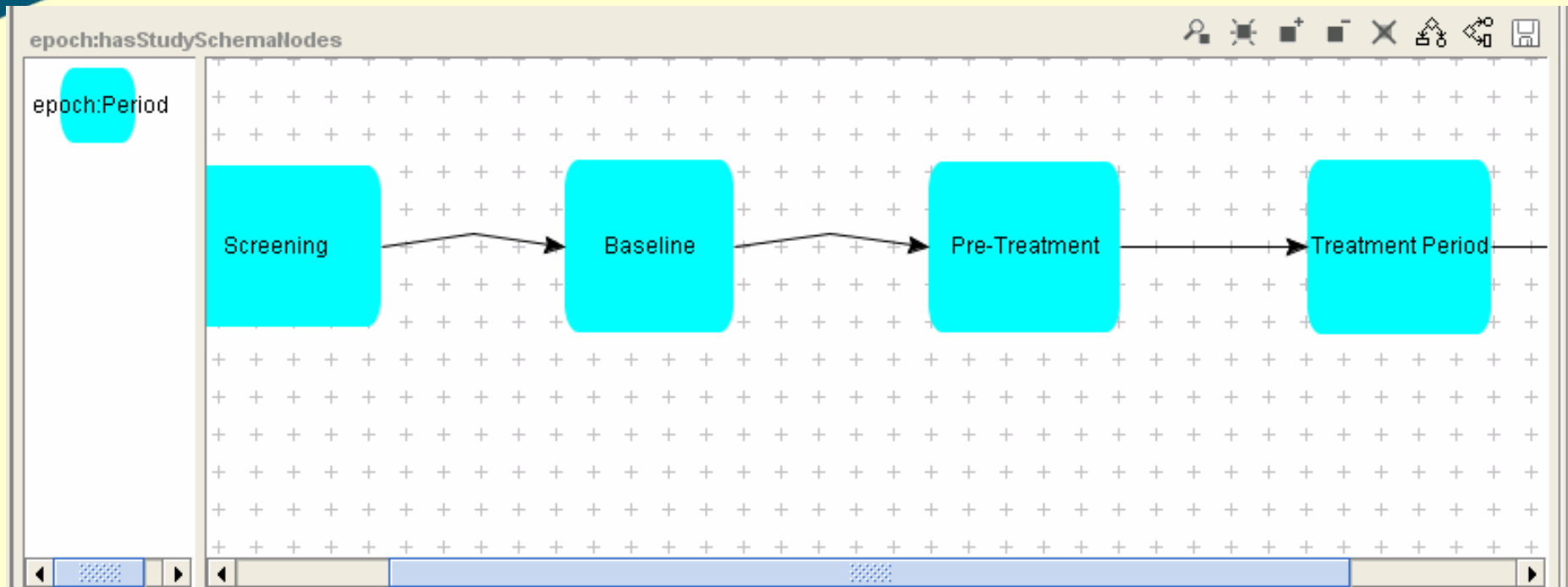
Screening

epoch:hasStudySchemaNodes

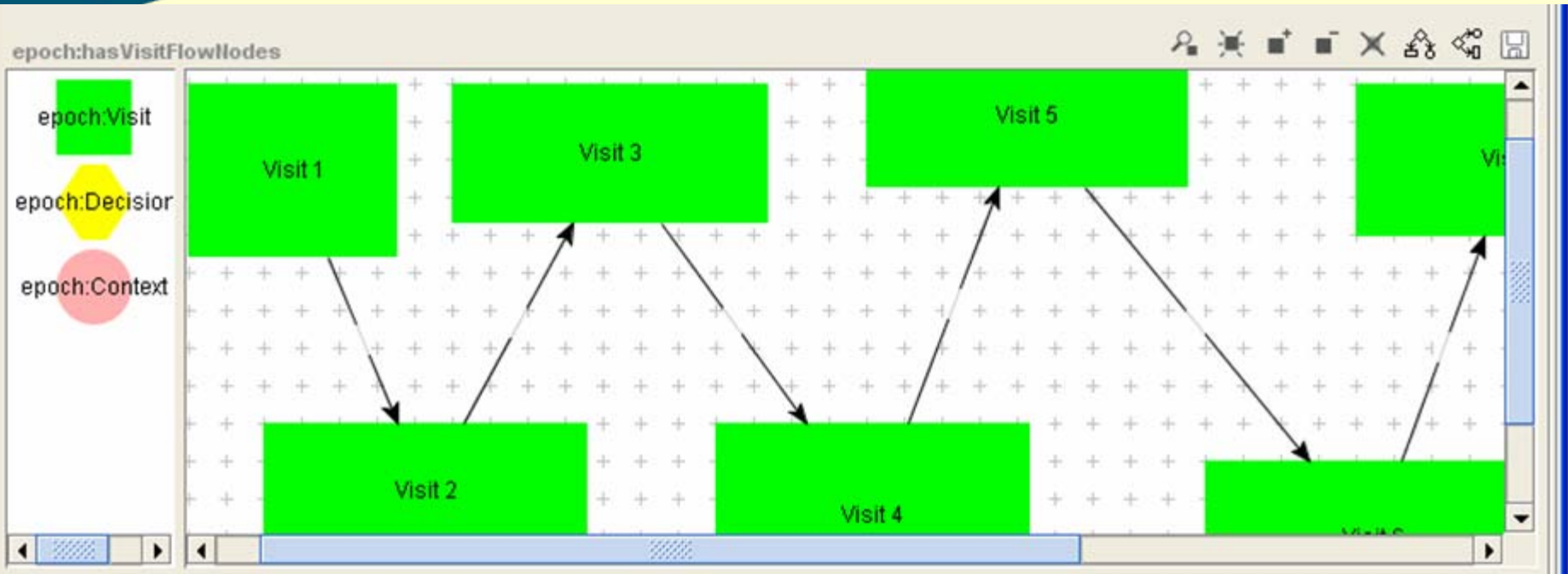
epoch:P

```
graph LR; Screening --> Baseline; Baseline --> Pre-Treatment;
```

Study Schema – a Temporal Sequence of Periods



Visit Flow – a Temporal Sequence of Visits



Visit

◆ Visit 1 (instance of epoch:Visit, internal name is Visit_22)

INDIVIDUAL EDITOR

For Individual: ◆ Visit 1 - Internal name: Visit_22 (instance of epoch:Visit)

Annotations

Property	Value	Lang
□ rdfs:comment		
□ rdfs:label	Visit 1	

epoch:hasVisitId

1

epoch:hasRepeatSpecification

◆ twice weekly until day 28 or discharge

epoch:hasVisitType

Scheduled

epoch:hasStartCondition

◆ Transplant Day +1

epoch:involvesMechanisticStudy

false

epoch:hasTransitionRestrictio

epoch:hasEndCondition

Visit – different Visit names

◆ Visit 1 (instance of epoch:Visit, internal name is Visit_22)

INDIVIDUAL EDITOR

For Individual: ◆ Visit 1 Internal name: (instance of epoch:Visit)

Annotations

Property	Value	Lang
□ rdfs:comment		
□ rdfs:label	Visit 1	

epoch:hasVisitId

epoch:hasRepeatSpecification ◆

epoch:hasVisitType

epoch:hasStartCondition ◆

epoch:involvesMechanisticStudy

epoch:hasTransitionRestrictio ◆

epoch:hasEndCondition ◆

Specimen Table

Mechanistic Study

Processing Instruction

Specimen Container

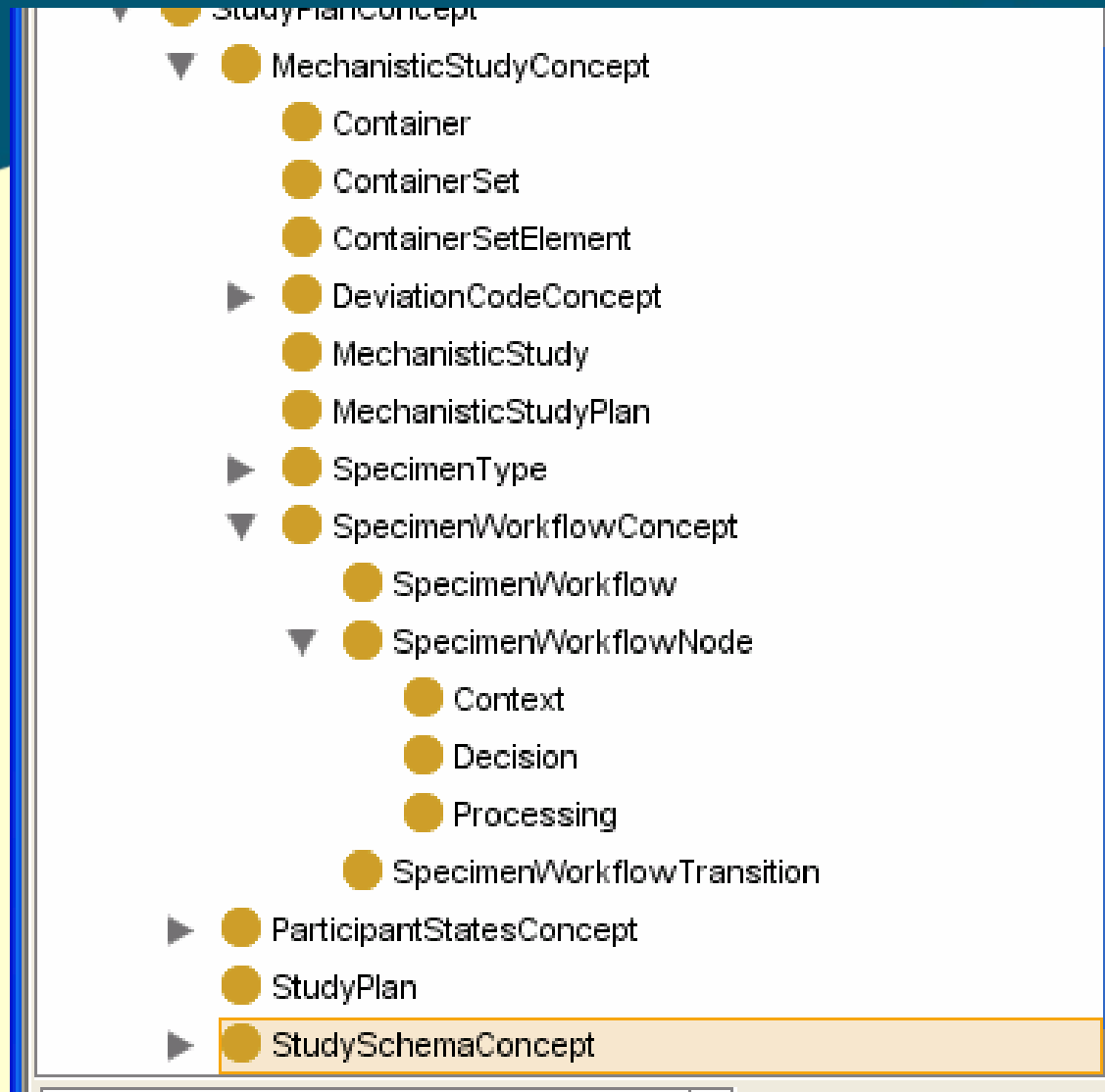
Assay

Specimen Workflow

		B		C			
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4	Leukaphereses WBC-Archive	2 x 10.9 MNP		into 8 cryovials and freeze			
5		Rus (RNA stabilization solution)		ovial			
		tubes provided by site (sample:)		ucted			
		DTA lavender top tube	10 ml	DO NOT SPIN. aliquot equally into 10 x 1.8 ml c			
11	Shipping Instruction	Destination	Final Destination	Assay Instructions	Assay Details	Collection Time Points/ Visits	Price
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NOTE:	Dry Ice Mon - Wed only	Fisher	Fisher	Archive		-1,2,3,4,5,6,7,8,9	5
	Ship ambient within 24 hours	Flow C	Flow C	Flow Cytometry		4,5,6,7,8,9	2
	Dry Ice Mon-Wed only	Fis		Archive		4,5,6	3
	Dry Ice Mon - Wed only	Fis				(coll	6
	Dry Ice Mon - Wed only	Fis				4,5,6	4
	Dry Ice Mon - Wed only	Fis				SC2, 6, 8 (
	Dry Ice Mon - Wed only	Fisher				relapse	
	Dry Ice Mon - Wed only	Fisher	Fisher	Archive		-1	6

previously met endpoint) reaches the 5-year end of study mark, they will have another end of study visit.

Protocol Model - Mechanistic Study Plan



Mechanistic Study Plan

The screenshot displays the Protégé OWL editor interface. The top menu bar includes File, Edit, Project, OWL, Code, Tools, Window, and Help. The toolbar contains various icons for file operations and editing. The main window is divided into several panes:

- Metadata**: Shows the Knowledge Tree on the left, listing various classes and properties such as `epoch:hasStudyInformation`, `epoch:hasSitePlan`, `epoch:hasStudyPlan`, `epoch:hasMechanisticStudyPlan`, `epoch:hasContainerSets`, `epoch:hasDeviat`, `epoch:hasStudyScher`, `epoch:hasArms`, `epoch:hasParticipants`, `epoch:hasPeriods`, `epoch:hasSite`, and `epoch:hasParticipantState`.
- INSTANCE EDITOR**: The central pane shows the instance editor for `Mechanistic Study Plan` (instance of `epoch:MechanisticStudyPlan`, internal name). It displays a table with the following properties and values:

Property	Value
<code>rdfs:comment</code>	
<code>rdfs:label</code>	echanistic Study Plan

Below the table, there are two sections for `epoch:hasContainerSets` and `epoch:hasMechanisticStudies`.

- epoch:hasContainerSets**:
 - Visit - 1 Blood Draw Kit
 - it
 - Leukapheresis Kit
- epoch:hasMechanisticStudies**:
 - Whole Blood - Flow Cytometry Panel Staining
 - Frozen PBMC-Archive
 - rofling
 - fling

At the bottom, there is a section for `epoch:hasDeviatCodeGroups` with the following items:

- Specimen Receiving
- Process And Aliquot
- Prepare for Visit
- Serum-Archive

Mechanistic Study Plan

epoch:hasContainerSets	epoch:hasMechanisticStudies
<ul style="list-style-type: none">◆ Visit 1 Blood Draw Kit◆◆ Leukapheresis Kit◆	<ul style="list-style-type: none">◆ Whole Blood - Flow Cytometry Panel Staining◆ Frozen PBMC-Archive◆ V^αβ TCRβ CDR3 Sequencing Profiling◆ Cytokine Profiling◆ Cytokine◆ Leukaphereses WBC - Archive◆ Whole Blood DNA Microarrays◆ Serum Archive
epoch:hasDeviationCodeGroups	
<ul style="list-style-type: none">◆ Specimen Receiving◆ Process And Aliquot◆ Prepare for Visit	









Mechanistic Study Plan

The screenshot displays a software interface for a 'Mechanistic Study Plan'. It is divided into three main sections:

- epoch:hasContainerSets**:
 - Visit 1 Blood Draw Kit
 - Leukapheresis Kit
- epoch:hasDeviationCodeGroups**:
 - Specimen Receiving
 - Process And Aliquot
 - Prepare for Visit
- epoch:hasMechanisticStudies** (highlighted with a red circle):
 - Whole Blood - Flow Cytometry Panel Staining
 - Frozen PBMC-Archive
 - Viral Load - Profiling
 - Cytokine - Profiling
 - Leukaphereses WBC - Archive
 - Whole Blood DNA - Archives
 - Screening









A Mechanistic Study

◆ Leukaphereses WBC - Archive

epoch:hasPriority	 	epoch:studyVisits
<input type="text" value="6"/>		◆ Visit 8
epoch:hasSpecimenWorkflow	  	◆ Baseline
◆ Leukaphereses WBC workflow		◆ Visit 6
epoch:hasAssay	  	
● Leukaphereses WBC .		

A Mechanistic Study

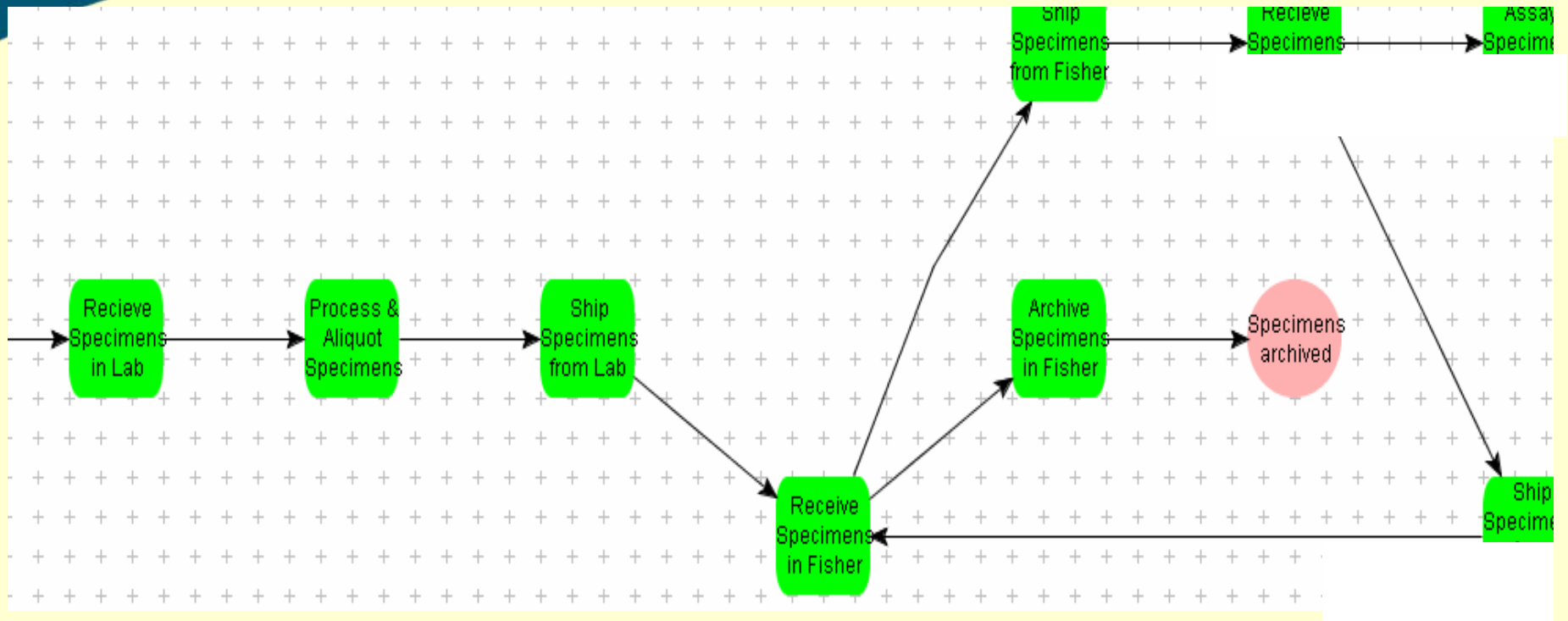
◆ Leukaphereses WBC - Archive

epoch:hasPriority	 	epoch:studyVisits
<input type="text" value="6"/>		◆ Visit 8
epoch:hasSpecimenWorkflow	  	◆ Baseline
◆ Leukaphereses WBC workflow		◆ Visit 6
epoch:hasAssay	  	
● Leukaphereses WBC .		

Specimen Workflow

The screenshot displays the Protégé OWL editor interface. On the left, the 'Knowledge Tree' panel shows a hierarchical structure of classes and properties. The 'epoch:hasSpecimenWorkflow' class is expanded, revealing its sub-classes and associated properties. The 'INSTANCE EDITOR' panel on the right shows the instance 'Leukaphereses WBC workflow' (an instance of 'epoch:SpecimenWorkflow'). Below this, the 'epoch:hasSpecimenWorkflowNodes' property is visualized as a directed graph on a grid. The graph shows a sequence of steps: 'Process & Aliquot Specimens' leads to 'Ship Specimens from Lab', which leads to 'Archive Specimens in Fisher', which leads to 'Specimens from Fisher', which leads to 'Specimen in NIH'. The 'epoch:hasSpecimenWorkflowNodes' property is also listed in the table above the graph.

Specimen Workflow



Mechanistic Study Plan

The screenshot displays a software interface for a 'Mechanistic Study Plan'. It is divided into two main columns. The left column contains three sections: 'epoch:hasContainerSets', 'epoch:hasDeviationCodeGroups', and 'epoch:hasMechanisticStudies'. The right column contains a single section titled 'epoch:hasMechanisticStudies'. A red circle highlights the 'epoch:hasContainerSets' section in the left column.

epoch:hasContainerSets

- ◆ Visit 1 Blood Draw Kit
- ◆
- ◆ Leukapheresis Kit
- ◆

epoch:hasDeviationCodeGroups

- ◆ Specimen Receiving
- ◆ Process And Aliquot
- ◆ Prepare for Visit

epoch:hasMechanisticStudies

- ◆ Whole Blood - Flow Cytometry Panel Staining
- ◆ Frozen PBMC-Archive
- ◆ V... Profiling
- ◆ C... ofiling
- ◆ C...
- ◆ Leukaphereses WBC - Archive
- ◆ W... es
- ◆ Serum Archive

Specimen Container Set

epoch:hasContainerSetName	epoch:visitsWhenUsed
<input type="text" value="Visit -1 Blood Draw Kit"/>	◆ Baseline
<div>epoch:hasDescription</div> <div><input type="text"/></div>	
<div>epoch:hasContainerSetEleme</div> <div><div>◆ Primary - 03ml Tempus Tube (3)</div><div>◆ Primary - 10ml Na Heparin Tube (1)</div><div>◆ Primary - 10ml K2EDTA Tube (1)</div></div>	

Specimen Container Set

epoch:hasContainerSetName	epoch:visitsWhenUsed
<input type="text" value="Visit - 1 Blood Draw Kit"/>	◆ Baseline
<div>epoch:hasDescription</div> <div><input type="text"/></div>	
<div>epoch:hasContainerSetEleme</div> <div><div>◆ Primary - 03ml Tempus Tube (3)</div><div>◆ Primary - 10ml Na Heparin Tube (1)</div><div>◆ Primary - 10ml K2EDTA Tube (1)</div></div>	

Specimen Container Set

epoch:hasContainerSetName	
Visit - 1 Blood Draw Kit	
epoch:hasDescription	
epoch:hasContainerSetElement	
◆ Primary - 03ml Tempus Tube (2)	
◆ Primary - 10ml Na Heparin Tube	
◆ Primary - 10ml K2EDTA Tube (1)	

epoch:hasDescription

epoch:hasCount

epoch:hasContainerName
● 10ml K2EDTA Tube

epoch:hasSpecimenType
● Whole Blood

Specimen Container Set

epoch:hasContainerSetName	Visit - 1 Blood Draw Kit
epoch:hasDescription	
epoch:hasContainerSetElement	<ul style="list-style-type: none">Primary - 03ml Tempus Tube (2)Primary - 10ml Na Heparin TubePrimary - 10ml K2EDTA Tube (1)

epoch:hasDescription	
epoch:hasCount	1
epoch:hasContainerName	10ml K2EDTA Tube
epoch:hasSpecimenType	Whole Blood

Specimen Container Ontology – using OWL Full meta model

SUBCLASS EXPLORER

For Project: SpecimenContainerModel

Asserted Hierarchy

- owl:Thing
 - rdfs:Class
 - owl:Class
 - ContainerMetaClass
 - SpecimenTypeMC
 - LabWare
 - Container
 - Tube
 - ABI
 - block
 - ACD
 - cryomold
 - FACS round bottom
 - K Oxalate
 - K2 EDTA
 - K3 EDTA
 - Li Heparin
 - Na Citrate
 - polypropylene tube
 - Serum
 - slide
 - SST
 - syringe

CLASS EDITOR

For Class: ContainerMetaClass (instance of owl:Class)

Property Value Lang

Property	Value	Lang
rdfs:comment		

rdfs:subClassOf

- owl:Class

Properties

Property	Cardinality	Type
additives	Multiple	owl:oneOf "RNA s"
closureColor	Single	owl:oneOf "blue"
closureType	Single	owl:oneOf "Hemoc"
comments	Single	string
discontinued	Single	boolean
discontinuedDate	Single	date
drawVolume	Single	string
insertColor	Single	string
labelType	Single	owl:oneOf "paper"
longName	Single	string
manufacturer	Single	owl:oneOf "Applie"
manufacturerId	Single	string
material	Single	owl:oneOf "glass"
processingRequirement	Single	ProcessingRequire
specimenTypes	Multiple	SpecimenTypeMC
storageRequirement	Single	StorageRequirem
suffixSeries	Single	string
tubeGroup	Single	owl:oneOf "primar
tubeSize	Single	string

Specimen Container Ontology – using OWL Full meta model

SUBCLASS EXPLORER
For Project: SpecimenContainerModel
Asserted Hierarchy

- owl:Thing
 - rdfs:Class
 - owl:Class
 - ContainerMetaClass**
 - SpecimenTypeMC
- LabWare
 - Container
 - Tube
 - ABI
 - block
 - ACD
 - cryomold
 - FACS round bottom
 - K Oxalate
 - K2 EDTA
 - K3 EDTA
 - Li Heparin
 - Na Citrate
 - polypropylene tube
 - Serum
 - slide
 - SST
 - syringe

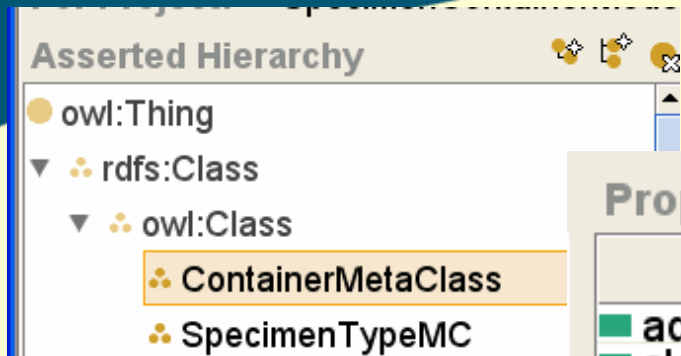
CLASS EDITOR
For Class: ContainerMetaClass (instance of owl:Class) ☐ Inferred View

Property	Value	Lang
rdfs:comment		

Properties

Property	Cardinality	Type
additives	Multiple	owl:oneOf"RNA s"
closureColor	Single	owl:oneOf"blue"
closureType	Single	owl:oneOf"Hemoc"
comments	Single	string
discontinued	Single	boolean
discontinuedDate	Single	date
drawVolume	Single	string
insertColor	Single	string
labelType	Single	owl:oneOf"paper"
longName	Single	string
manufacturer	Single	owl:oneOf"Applie"
manufacturerId	Single	string
material	Single	owl:oneOf"glass"
processingRequire	Single	ProcessingRequire
specimenTypes	Multiple	SpecimenTypeMC
storageRequirement	Single	StorageRequirem
suffixSeries	Single	string
tubeGroup	Single	owl:oneOf"primar
tubeSize	Single	string

Specimen Container Ontology – using OWL Full meta model



Properties		
Property	Cardinality	Type
additives	Multiple	owl:oneOf{"RNA s"
closureColor	Single	owl:oneOf{"blue" "
closureType	Single	owl:oneOf{"Hemoc
comments	Single	string
discontinued	Single	boolean
discontinuedDate	Single	date
drawVolume	Single	string
insertColor	Single	string
labelType	Single	owl:oneOf{"paper"
longName	Single	string
manufacturer	Single	owl:oneOf{"Applie
manufacturerId	Single	string
material	Single	owl:oneOf{"glass"
processingRequirement	Single	ProcessingRequir
specimenTypes	Multiple	SpecimenTypeMC
storageRequirement	Single	StorageRequireme
suffixSeries	Single	string
tubeGroup	Single	owl:oneOf{"primar
tubeSize	Single	string

Specimen Container Ontology

Metadata (SpecimenCo...rModel.owl) OWLClasses Properties Individuals Forms

SUBCLASS EXPLORER

For Project: SpecimenContainerModel

Asserted Hierarchy

- owl:Thing
 - rdfs:Class
 - owl:Class
 - ContainerMetaClass
 - SpecimenTypeMC
 - LabWare
 - Container
 - Tube
 - ABI
 - block
 - ACD
 - cryomold
 - FACS round bottom
 - K Oxalate
 - K2 EDTA
 - 10ml K2EDTA Tube
 - K3 EDTA
 - Li Heparin
 - Na Citrate
 - polypropylene tube
 - Serum
 - slide
 - SST

CLASS EDITOR

For Class: 10ml K2EDTA Tube - Internal name:

☐ Inferred View

rdfs:subClassOf

- K2 EDTA

Property	Cardinality	Type
----------	-------------	------

closureColor: lavender

closureType: Hemogard

comments:

discontinuedDate:

drawVolume: 10 ml

insertColor:

labelType: see thru

longName: 10 ml K2 EDTA (K2 EDTA -- la

manufacturer: Becton Dickinson

manufacturerId: 366643

material: plastic

suffixSeries: -5A to -5Z

tubeGroup: primary

tubeSize: 16 x 100 mm

discontinued: false

processingRequirer: k2_edta_processing_instr

storageRequirement: k2_edta_storage_inst.

additives:

Value	Type
K2 EDTA	string

specimenTypes:

- Whole Blood

A Hierarchy of Specimen Containers

- ▼ ● LabWare
 - ▼ ● Container
 - ▼ ● Tube
 - ABI
 - block
 - ACD
 - cryomold
 - FACS round bottom
 - K Oxalate
 - ▼ ● K2 EDTA
 - 10ml K2EDTA Tube
 - K3 EDTA
 - Li Heparin
 - ▶ ● Na Citrate
 - polypropylene tube
 - Serum
 - slide
 - ▶ ● SST

A Specimen Container

- K2 EDTA
- 10ml K2EDTA Tube
- K2 EDTA

closureColor	<input type="text" value="lavendar"/>	longName	<input type="text" value="10 ml K2 EDTA (K2 EDTA -- la"/>	discontinued	<input type="text" value="false"/>				
closureType	<input type="text" value="Hemogard"/>	manufacturer	<input type="text" value="Becton Dickinson"/>	processingRequirer	<input type="text" value="k2_edta_processing_instr"/>				
comments	<input type="text"/>	manufacturerId	<input type="text" value="366643"/>	storageRequiremen	<input type="text" value="k2_edta_storage_inst."/>				
discontinuedDate	<input type="text"/>	material	<input type="text" value="plastic"/>	additives	<table><thead><tr><th>Value</th><th>Type</th></tr></thead><tbody><tr><td>K2 EDTA</td><td>string</td></tr></tbody></table>	Value	Type	K2 EDTA	string
Value	Type								
K2 EDTA	string								
drawVolume	<input type="text" value="10 ml"/>	suffixSeries	<input type="text" value="-5A to -5Z"/>	specimenTypes	<input type="text" value="● Whole Blood"/>				
insertColor	<input type="text"/>	tubeGroup	<input type="text" value="primary"/>						
labelType	<input type="text" value="see thru"/>	tubeSize	<input type="text" value="16 x 100 mm"/>						

Assay Ontology – using OWL Full meta model

The screenshot displays the Protege ontology editor interface. At the top, there are tabs for 'Metadata (assaymodel.owl)', 'OWLClasses', 'Properties', 'Individuals', and 'Forms'. The 'SUBCLASS EXPLORER' on the left shows a hierarchy starting from 'owl:Thing', through 'rdfs:Class' and 'owl:Class', to 'AssayMC'. The 'CLASS EDITOR' on the right is set for the 'AssayMC' class. It features a table with 'Property' and 'Value' columns, and a 'Lang' column. The table lists various properties such as 'analysisTimeline', 'background', 'batchingRequirements', 'collectionTimepoints', 'description', 'patientSets', 'performedBy', 'specimenCollectionRequirements', 'specimenContainerRequirements', 'turnaroundTime', and 'validationOfResults', all with values in parentheses indicating they are single strings. It also lists meta-properties like 'owl:equivalentClass', 'protege:abstract', 'protege:classificationStatus', 'protege:inferredSubclassOf', and 'protege:inferredSuperclassOf'. The bottom of the interface includes a 'Superclasses' section showing 'owl:Class' and a 'Disjoints' section.

Metadata (assaymodel.owl) | OWLClasses | Properties | Individuals | Forms

SUBCLASS EXPLORER

For Project: ● AssayModel

Asserted Hierarchy

- owl:Thing
 - rdfs:Class
 - owl:Class
 - AssayMC**
- Assay
 - Whole Blood - Flow Cytom
 - AlloELISPOT
 - HLA
 - Gene expression in urine
 - Leukaphereses WBC - Arc
 - Whole Blood - DNA HLA G
 - Whole Blood - Gene Expre
 - CSF Pellet - Gene Express
 - Flow Cytometry
 - Trans-vivo Delayed Type H
 - Serum Alloantibodies and H
 - Histologic Assessment of A

CLASS EDITOR

For Class: ● AssayMC (instance of owl:Class) ☐ Inferred View

Annotations

Property	Value	Lang
analysisTimeline	(single string)	
background	(single string)	
batchingRequirements	(single string)	
collectionTimepoints	(single string)	
description	(single string)	
patientSets	(single string)	
performedBy	(single string)	
specimenCollectionRequirements	(single string)	
specimenContainerRequirements	(single string)	
turnaroundTime	(single string)	
validationOfResults	(single string)	
owl:equivalentClass		
protege:abstract	(single boolean)	
protege:classificationStatus		
protege:inferredSubclassOf		
protege:inferredSuperclassOf		

Properties and Restrictions

Superclasses

- owl:Class

Disjoints

Assay Ontology – using OWL Full meta model

The screenshot displays the Protege ontology editor interface. On the left, the 'Asserted Hierarchy' pane shows a tree structure starting with 'owl:Thing', followed by 'rdfs:Class', 'owl:Class', and 'AssayMC'. The 'AssayMC' class is highlighted. On the right, the 'Properties and Restrictions' pane lists various properties for the 'AssayMC' class. These properties include several data types (single string, single boolean) and object types (owl:equivalentClass, protege:classificationStatus, protege:inferredSubclassOf, protege:inferredSuperclassOf).

Asserted Hierarchy

- owl:Thing
 - rdfs:Class
 - owl:Class
 - AssayMC

Properties and Restrictions

- analysisTimeline (single string)
- background (single string)
- batchingRequirements (single string)
- collectionTimepoints (single string)
- description (single string)
- patientSets (single string)
- performedBy (single string)
- specimenCollectionRequirements (single string)
- specimenContainerRequirements (single string)
- turnaroundTime (single string)
- validationOfResults (single string)
- owl:equivalentClass
- protege:abstract (single boolean)
- protege:classificationStatus
- protege:inferredSubclassOf
- protege:inferredSuperclassOf

Assay Ontology

Metadata (assaymodel.owl)

OWLClasses

Properties

Individuals

Forms

SUBCLASS EXPLORER

For Project: AssayModel

Asserted Hierarchy

owl:Thing

rdfs:Class

owl:Class

AssayMC

Assay

Whole Blood - Flow Cytometry Panel Staining

AlloELISPOT

HLA

Gene expression in urine

Leukaphereses WBC

Whole Blood - DNA HLA Genotypes

Whole Blood - Gene Expression Profiling

CSF Pellet - Gene Expression Profiling

Flow Cytometry

Trans-vivo Delayed Type Hypersensitivity (DTH)

Serum Alloantibodies and HLA cross-match

Histologic Assessment of Allograft - Kidney Biop

CLASS EDITOR

For Class: Whole Blood - Flow Cytometry Panel Staining - Internal ☐ Inferred View

background

Process and achievement of tolerance may be closely related to the types and relative frequencies of different immune cell

specimenCollectionRequirements

6-10 ml whole blood within 36 hours of blood draw

batchingRequirements

None - Real time assay

validationOfResults

1 month for validation from Data Center and Assay group

collectionTimepoints

0,3,6,7,8,9,10,11,12

description

subsets

mature, costimulation, antigen presentation

23 6 B 11 V alpha 24 CD8 C

specimenContainerRequ

10 ml glass Na Heparin Gre tube

turnaroundTime

3 days

analysisTimeline

6 months (can take longer c on type of analysis)

patientSets

Assay Ontology

▼ ● Assay

- Whole Blood - Flow Cytometry Panel Staining
- AlloELISPOT
- HLA
- Gene expression in urine
- Leukaphereses WBC
- Whole Blood - DNA HLA Genotypes
- Whole Blood - Gene Expression Profiling
- CSF Pellet - Gene Expression Profiling
- Flow Cytometry
- Trans-vivo Delayed Type Hypersensitivity (DTH)
- Serum Alloantibodies and HLA cross-match
- Histologic Assessment of Allograft - Kidney Biop

An Assay

● Whole Blood - Flow Cytometry Panel Staining

background

Process and achievement of tolerance may be closely related to the types and relative frequencies of different immune cell

specimenCollectionRequirements

6-10 ml whole blood within 36 hours of blood draw

batchingRequirements

None - Real time assay

validationOfResults

1 month for validation from Data Center and Assay group

collectionTimepoints

0,3,6,7,8,9,10,11,12

performedBy

description

Examination of PBMC surface molecule expression will be performed using 5 color antibody combinations. The monoclonal

specimenContainerRequirements

10 ml glass Na Heparin Green Top tube

turnaroundTime

3 days

analysisTimeline

6 months (can take longer depending on type of analysis)


patientSets


Virtual Trial Data Model - Observation


epoch:Observation (instance of epoch:DataModelMC)







CLASS EDITOR + - F T



For Class: epoch:Observation (instance of epoch:DataModelMC) ☐ Inferred View



 Annotations


Property	Value	Lang
 rdfs:comment		
<div></div>		

 **Properties and Restrictions**

-  epoch:associatedVisitRecord (single epoch:VisitRecord)
-  epoch:hasCode (single string)
- ▼  epoch:hasValue (single) (someValuesFrom epoch:Expression)
 -  epoch:Expression
- ▼  temporal:hasValidTime (multiple temporal:ValidTime) (minCardinality 1)
 -  1 [from temporal:ExtendedProposition]

 **Superclasses**  **Disjoints**

-  epoch:ParticipantRecord
-  temporal:ExtendedPrimitiveProposition

 ☐ Logic View ☒ Properties View


Virtual Trial Data Model - VisitRecord

epoch:VisitRecord (instance of epoch:DataModelMC)







CLASS EDITOR

For Class: epoch:VisitRecord (instance of epoch:DataModelMC) ☐ Inferred View



Annotations

Property	Value	Lang
 rdfs:comment		

Properties and Restrictions

-  epoch:hasParticipantId (single string)
-  epoch:hasSiteId (single string)
-  epoch:hasStudyId (single string)
-  epoch:hasVisitId (single string)
- ▼  temporal:hasValidTime (multiple temporal:ValidTime) (minCardinality 1)
  1 [from temporal:ExtendedProposition]

Superclasses

-  temporal:ExtendedPrimitiveProposition
-  epoch:ParticipantRecord

Disjoints

Logic View ☒ Properties View

Anchor Point - Transplant

Transplant (instance of epoch:TemporalAnchorPoint, internal name is epoch:AnchorPoint_1)

INDIVIDUAL EDITOR

For Individual: ♦ Transplant - Internal name: epoch:AnchorPoint_1

Annotations

Property	Value	Lang
rdfs:comment		
rdfs:label	Transplant	

epoch:hasName ✖ temporal:hasTime + ✖

Transplant [] 00 : 00 : 00

temporal:hasGranularity ✖ epoch:hasMappingRule ✖ ✖ ✖

days ▼ ♦ SetTransplant

SWRL Rule to set Transplant Time

```
Observation(?o) ^  
associatedVisitRecord(?o, ?vrecord) ^  
hasParticipantId(?vrecord, ?pid) ^  
hasCode(?o, ?code) ^  
swrlb:equal(?code, "transplant") ^  
temporal:hasValidTime(?o, ?vtO) ^  
TemporalAnchorPoint(?a) ^  
hasName(?a, "Transplant")  
→ temporal:hasValidTime(?a, ?vtO)
```



OK

Cancel

Visit Time Window

◆ Transplant + 28days +/- 3days (instance of temporal:RelativeVariableInterval, internal name is RelativeVar...

INDIVIDUAL EDITOR

For Individual: ◆ Transplant + 28days +/- 3days - Internal name:

Annotations

Property	Value	Lang
rdfs:comment		
rdfs:label	Transplant + 28days +/- 3days	

temporal:hasPolarity ✕ after

temporal:hasLowVariable ◆ 3 days

temporal:hasAnchor ◆ Transplant

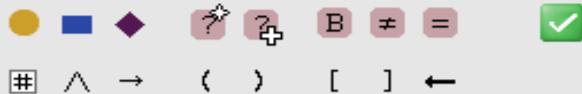
temporal:hasOffset ◆ 28 days

temporal:hasHighVariable ◆ 3 days

Visit Time constraint as a SWRL rule

Check if the participant's visits occurred within the visit time window specifications

```
VisitRecord(?vrecord) ∧  
hasVisitId(?vrecord, ?vid1) ∧  
hasParticipantId(?vrecord, ?pid) ∧  
temporal:hasValidTime(?vrecord, ?vtO) ∧  
Visit(?v) ∧  
hasVisitId(?v, ?vid2) ∧  
swrlb:equal(?vid1, ?vid2) ∧  
hasStartCondition(?v, ?vsc) ∧  
temporal:inside(?vtO, ?vsc)  
→
```



OK

Cancel

Constraints expressed as SWRL rules

On days that both immunotherapy and omalizumab are administered, omalizumab will be injected 60 minutes after the immunotherapy.

```
Patient(?p) ∧  
hasExtendedEvent(?p, ?eevent1) ∧ hasExtendedEvent(?p, ?eevent2) ∧  
temporal:hasValue(?eevent1, ?event1) ∧ temporal:hasValidTime(?eevent1, ?event1VT) ∧  
temporal:hasTime(?event1VT, ?event1Time) ∧ temporal:hasValue(?eevent2, ?event2) ∧  
temporal:hasValidTime(?eevent2, ?event2VT) ∧ temporal:hasTime(?event2VT, ?event2Time) ∧  
hasVisit(?event1, ?v) ∧ hasVisit(?event2, ?v) ∧  
hasActivity(?event1, ?a1) ∧ hasName(?a1, "Omalizumab") ∧  
hasActivity(?event2, ?a2) ∧ hasName(?a2, "Immunotherapy") ∧  
temporalOp:before(?event2Time, ?event1Time) ∧  
temporalOp:durationMinutesLessThan(60, ?event2Time, ?event1Time) → NonconformingPatient(?p)
```



OK



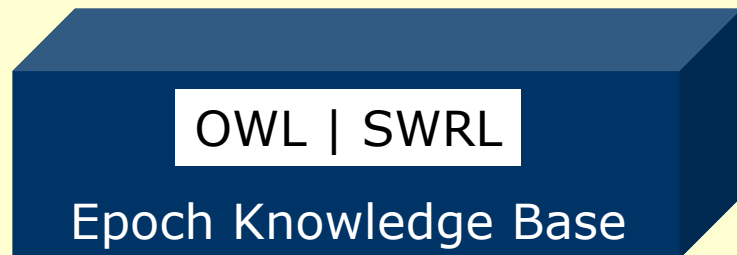
Cancel

ITN Informatics Core at Stanford

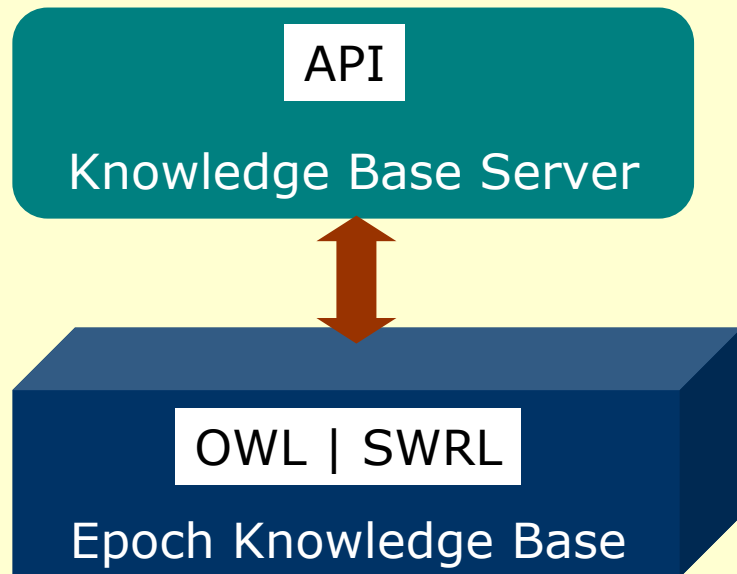
The goals of our collaboration are to

- Design tools to help acquire and maintain knowledge about protocol and assay designs
- Use this knowledge to drive data collection during a trial
- Implement querying methods to support trial monitoring, protocol tracking, and ad hoc data analysis

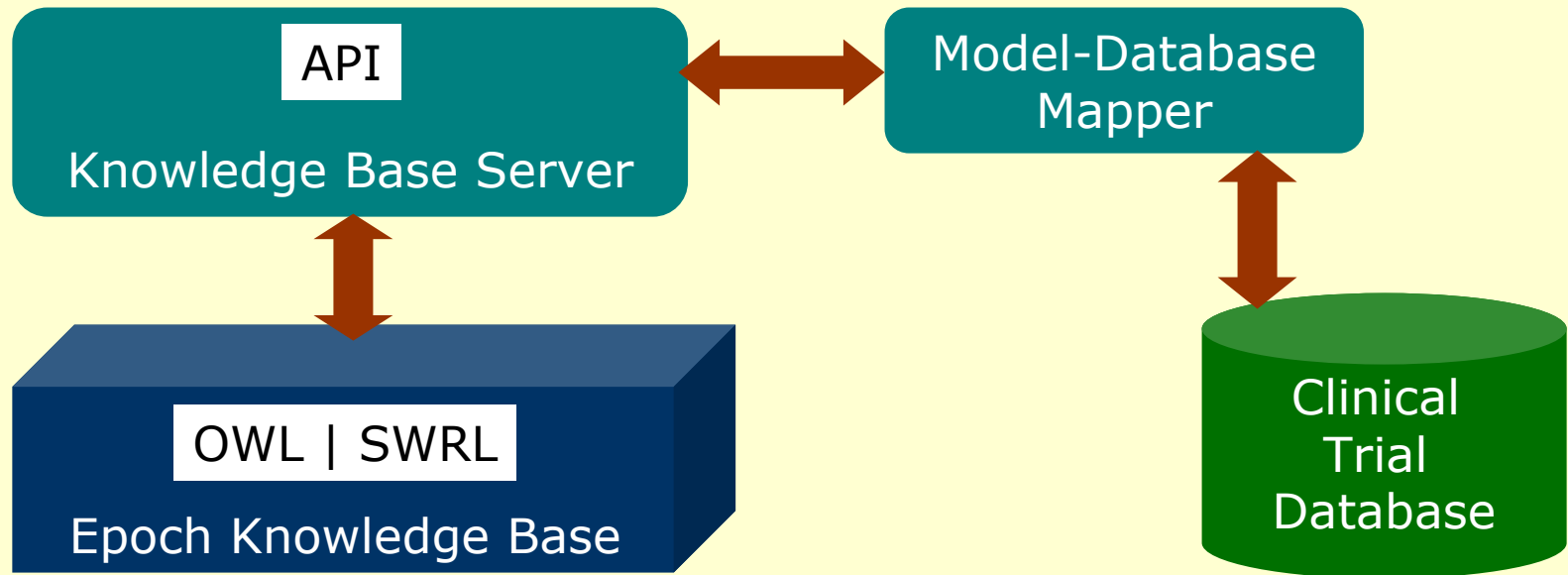
Epoch Architectural Plan



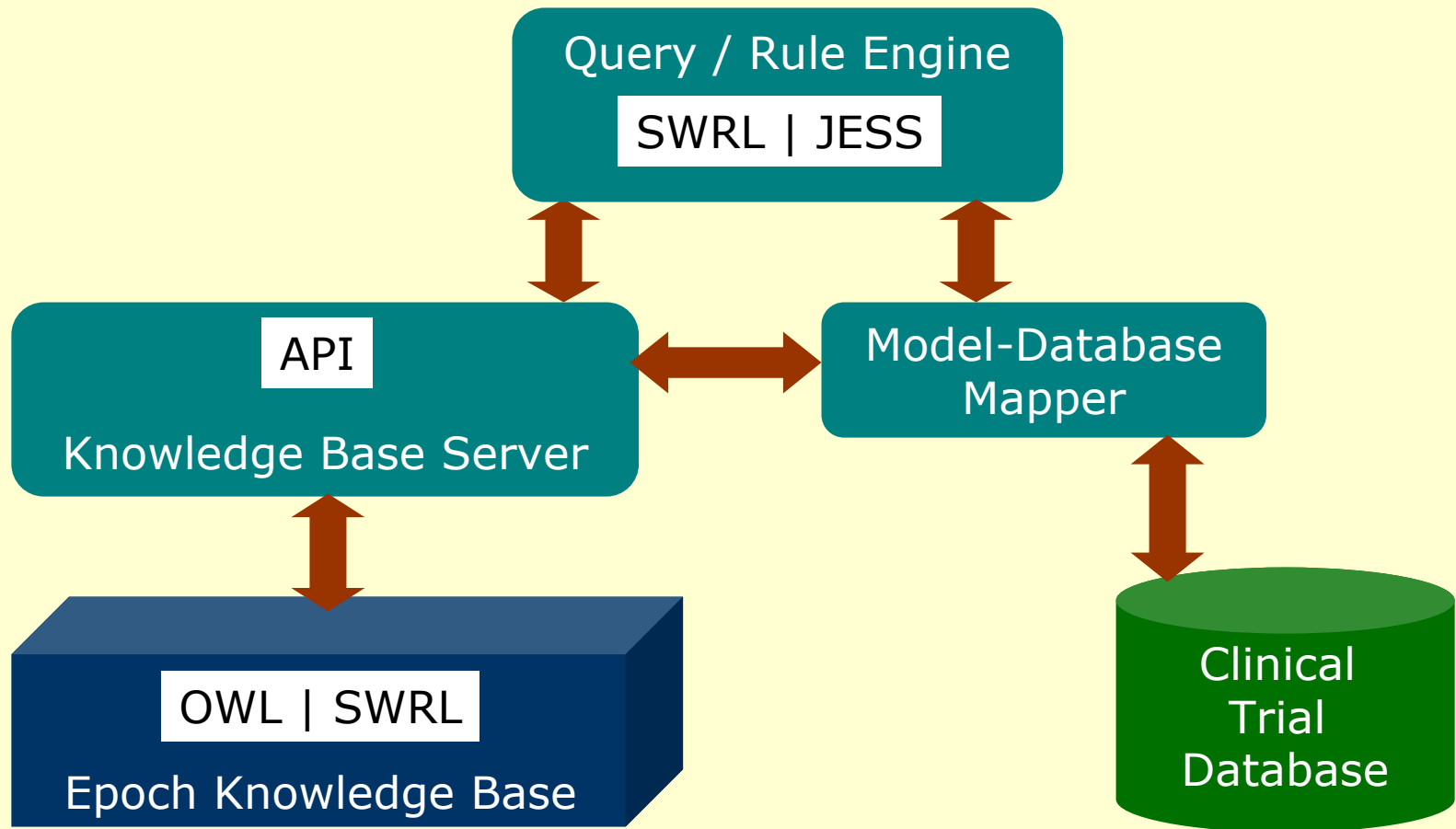
Epoch Architectural Plan



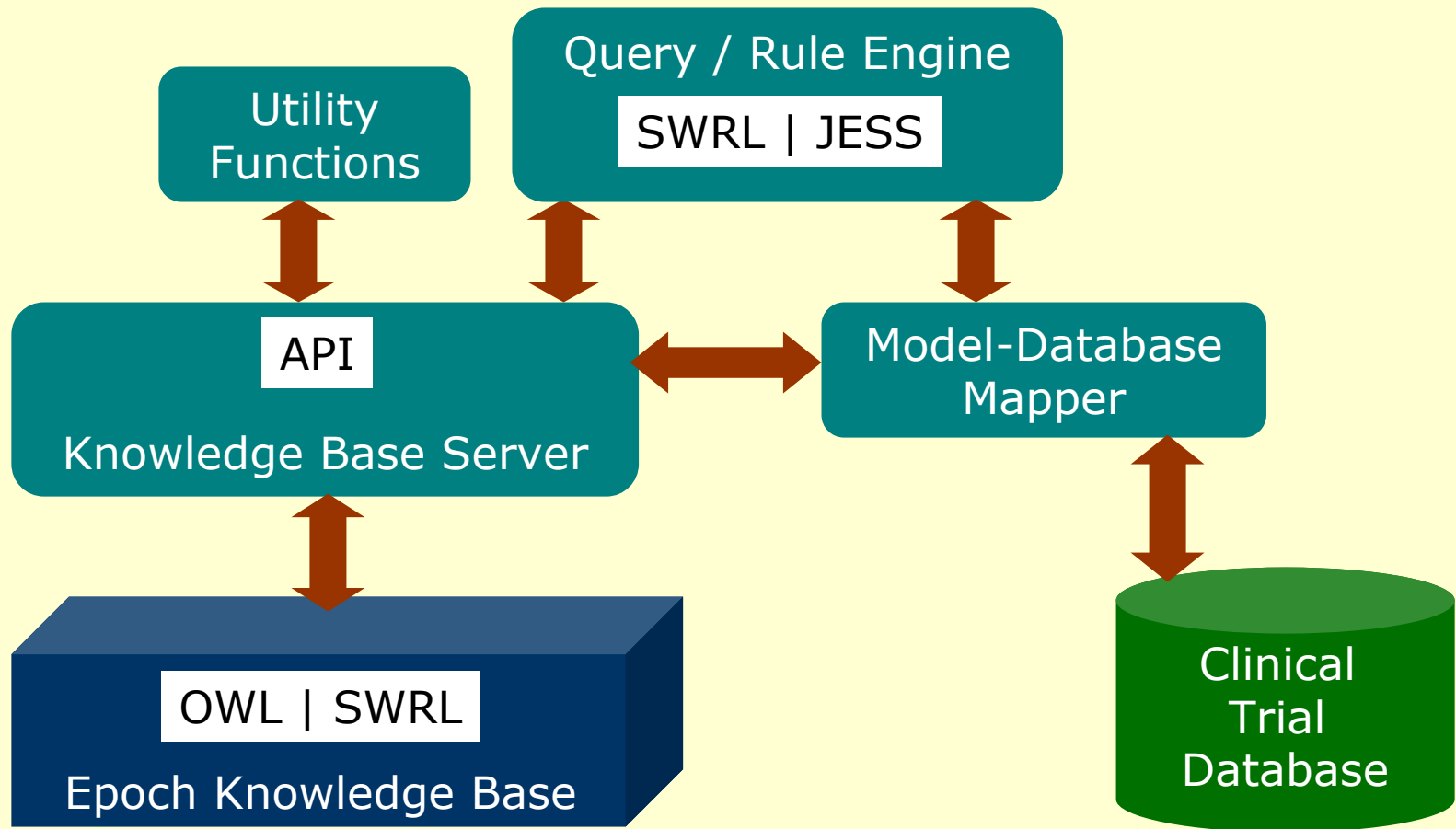
Epoch Architectural Plan



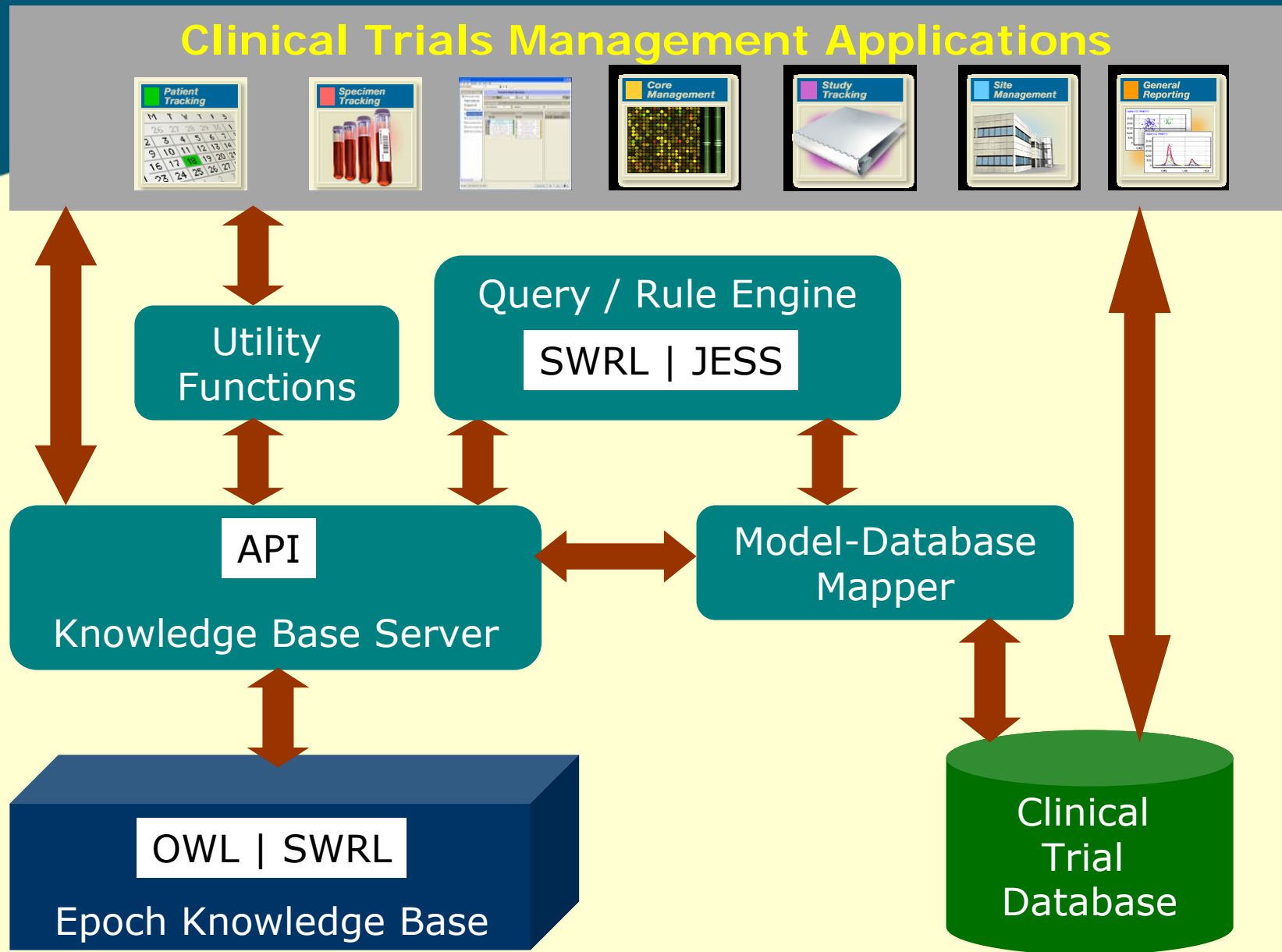
Epoch Architectural Plan



Epoch Architectural Plan



Epoch Architectural Plan



Configuration of ImmunoTrak – the Specimen Workflow Application

ImmunoTrak

File Edit View Applications Tools Window Help

Enter PID or Barcode: <scan>

ImmunoTrak Navigator

- Specimen Tracking
- Import Container Sets
- Prepare for Visit
- Receive Specimens in Lab
- Process & Aliquot Specimen**
- Ship Specimens from the Lab
- Receive Specimens at Flow C
- Record Flow Cytometry Proce
- Import Fisher Accessioning Lo

IMMUNOTRAK: Process & Aliquot Specimens

Worklist Filter: Selected Items Selected

Activity Details

Scan Tube Barcode <scan> Participant Visit Status

Inputs		Outputs	
Barcode		Barcode	
<Scan CSF Kit>	✓	<Scan Serum-SST Cryovial>	?
<Scan Leukapheresis Kit>	✓	yovial>	?
1 <Scan Visit -1 Blood Draw Kit>	✓	4 Cryovial>	?
<Scan Visit 2-9 Blood Draw Kit>	✓	yovial>	?
<Scan Visit UN Blood Kit>	✓	4 Tube>	?
		<Scan CSF supernatant Cryovial>	?

Work Item Details

CSF Kit: <Unknown Item>

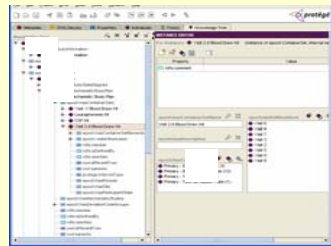
App Status Login successful for user scierra.

Finish and Save Clear Cancel Help

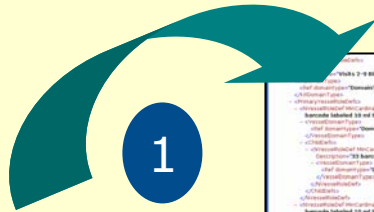
ImmunoTrak Configuration File

```
</PrimaryVesselRoleDefs>
</NKitType>
- <NKitType Name="Visits 2-9 Blood Kit" Description="Visits 2-9 Blood Kit">
  - <KitDomainType>
    <Ref domaintype="DomainType" uniquekey="{DomainType V2 Blood Kit}" />
  </KitDomainType>
  - <PrimaryVesselRoleDefs>
    - <NVesselRoleDef MinCardinality="0" MaxCardinality="-1" DefaultCardinality="2" Description="2
      barcode labeled 10 ml SST Tubes">
      - <VesselDomainType>
        <Ref domaintype="DomainType" uniquekey="{DomainType SST Tube}" />
      </VesselDomainType>
      - <ChildDefs>
        - <NVesselRoleDef MinCardinality="0" MaxCardinality="-1" DefaultCardinality="33"
          Description="33 barcode labeled Serum-SST Cryovials">
          - <VesselDomainType>
            <Ref domaintype="DomainType" uniquekey="{DomainType Serum Tube}" />
          </VesselDomainType>
          </NVesselRoleDef>
        </ChildDefs>
      </NVesselRoleDef>
    - <NVesselRoleDef MinCardinality="0" MaxCardinality="-1" DefaultCardinality="1" Description="1
      barcode labeled 10 ml Na Heparin Tube">
      - <VesselDomainType>
        <Ref domaintype="DomainType" uniquekey="{DomainType NaHeparin Tube}" />
      </VesselDomainType>
      </NVesselRoleDef>
    - <NVesselRoleDef MinCardinality="0" MaxCardinality="-1" DefaultCardinality="12" Description="12
      barcode labeled 08 ml CPT Tubes">
      - <VesselDomainType>
        <Ref domaintype="DomainType" uniquekey="{DomainType CPT Tube}" />
      </VesselDomainType>
      - <ChildDefs>
        - <NVesselRoleDef MinCardinality="0" MaxCardinality="-1" DefaultCardinality="10"
          Description="10 barcode labeled PBMC Cryovials">
```

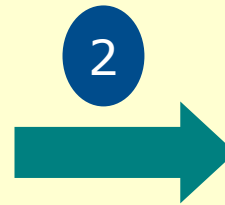
Configuration of ImmunoTrak – the Specimen Workflow Application



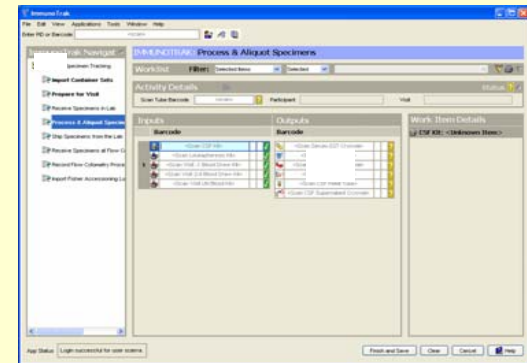
Epoch
Knowledge
Base



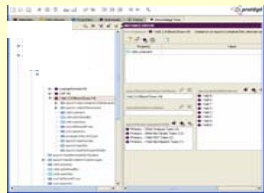
ImmunoTrak
Configuration



ImmunoTrak –
Specimen Workflow

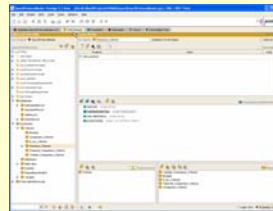


Ontology Mapping to generate XML Document



Epoch
Ontology

SWRL

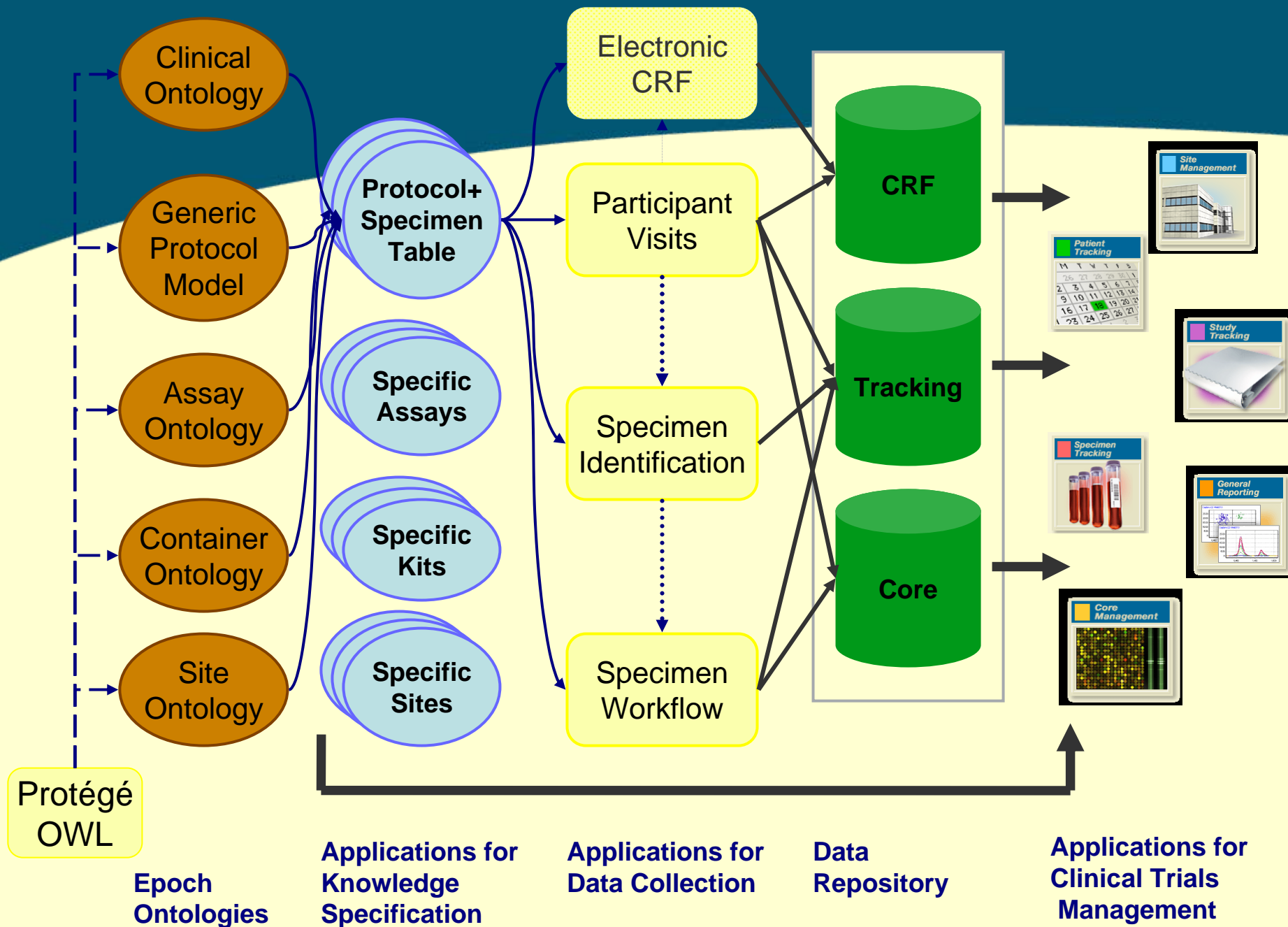


XML Document
Ontology



ImmunoTrak
Configuration XML

```
Protocol(?p) ^ hasSitePlan(?p, ?sp) ^ hasStudySites(?sp, ?site) ^  
hasSiteID(?site, ?siteID) ^ hasParticipant(?site, ?participants) ^  
hasParticipantIDs(?participant, ?participantID) ^  
hasStudyInformation(?sp, ?studyInfo) ^ hasStudyID(?studyInfo,  
?hasStudyID)  
-> XMLDocument(?p) ^ hasNodeName(?p, "Study") ^  
XMLComponent(?participant) ^ hasNodeName(?participant,  
"Participant") ^ hasComponents(?p, ?participant) ^  
hasAttribute(?participant, ?participantID) ^  
hasAttributeName(?participantID, "id">
```



What our approach buys us

- A centralized, modifiable repository of the knowledge to drive site-oriented applications
- The ability to use reference ontologies to structure ITN knowledge
- A scalable architecture that can lead to computer-supported trial design
- The ability to use logic for inferring relationships among the data