"A collaborative project to
develop a universal framework for
encoding and disseminating electronic clinical guidelines"

The SAGE Project

Standards-Based Sharable Active Guideline Environment

"A collaborative project to develop a universal framework for sharing health knowledge in the form of computable clinical practice guidelines"

21 December 2005

The SAGE Project
Standards-Based Sharable Active Guideline Environment

Hello….

- Robert Abarbanel, MD, PhD
- Jim McClay, MD
- Craig Parker, MD, MS
- Guy Mansfield, PhD
- David Berg

Agenda

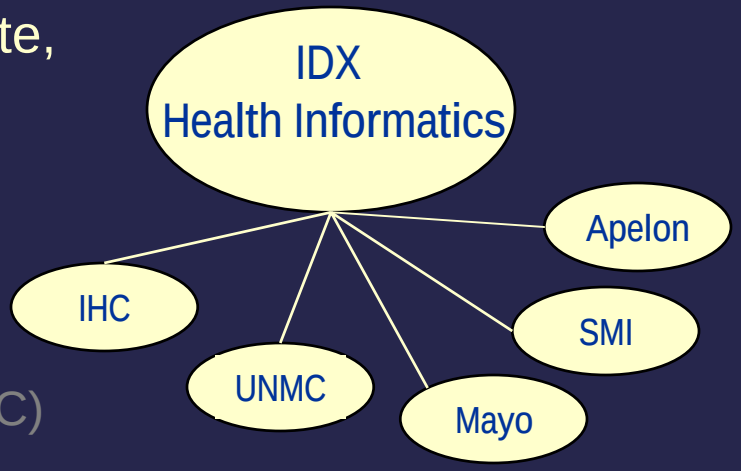
1. SAGE mission and goals
2. Technical details
   - Guideline model
   - Execution engine
   - Interfaces
3. Accomplishments
4. 2006 Plan
5. *Azyxxi Collaboration*

The SAGE Project
Standards-Based Sharable Active Guideline Environment

Project Overview

Standards-based **S**harable **A**ctive **G**uideline **E**nvironment

- An R&D consortium to develop the technology infrastructure to enable computable clinical guidelines, that will be shareable and interoperable across multiple clinical information system platforms
- Scope: 3 year, $18 M, multi-site, collaborative project



- Partners in the project are:
  - IDX Systems Inc.
  - Apelon, Inc.
  - Intermountain Healthcare (IHC)
  - Mayo Clinic
  - Stanford Medical Informatics (SMI)
  - University of Nebraska Medical Center (UNMC)
- Funded in part by: NIST Advanced Technology Program

Cooperative Agreement Number 70NANB1H3049

NATIONAL HEALTH INFORMATION INFRASTRUCTURE 2003

DEVELOPING A NATIONAL ACTION AGENDA FOR NHII

JUNE 30—JULY 2, 2003 • WASHINGTON, DC

Sponsored by the Department of Health and Human Services (DHHS), the purpose of the conference was to develop a consensus for a national action agenda to guide the further development of NHII.

Safety and Quality Track Recommendation:

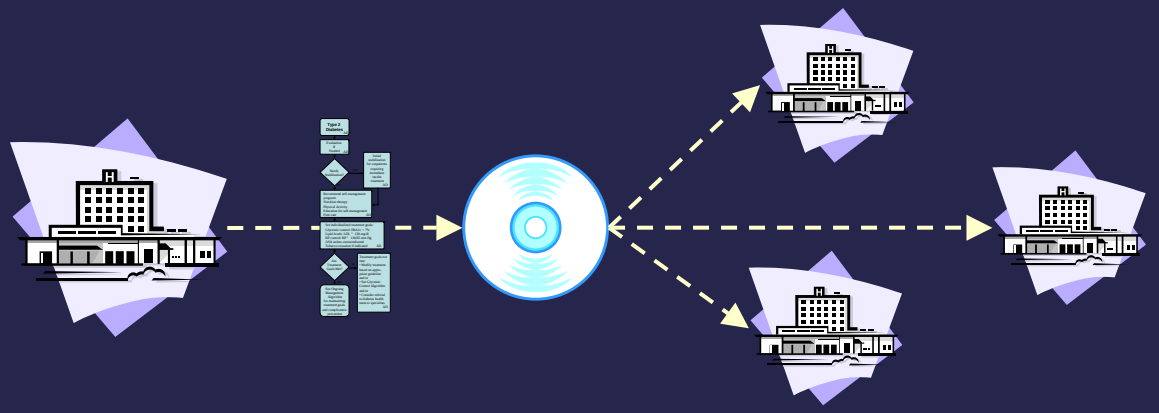
"Create central resources and processes that serve as a library of nationally vetted clinical guidelines and knowledge sources in standardized executable format using a standard guideline authoring tool consistent with the needs of patient safety and quality."

The SAGE Project
Standards-Based Sharable Active Guideline Environment

SAGE Project Goals

The primary goal: Develop a Standards-Based Sharable Active Guideline Environment with which:

- Health experts can author and encode clinical practice guidelines in a standard computable format, and
- Health care organizations throughout the nation can deploy those guidelines easily within any standards-conforming clinical information system.

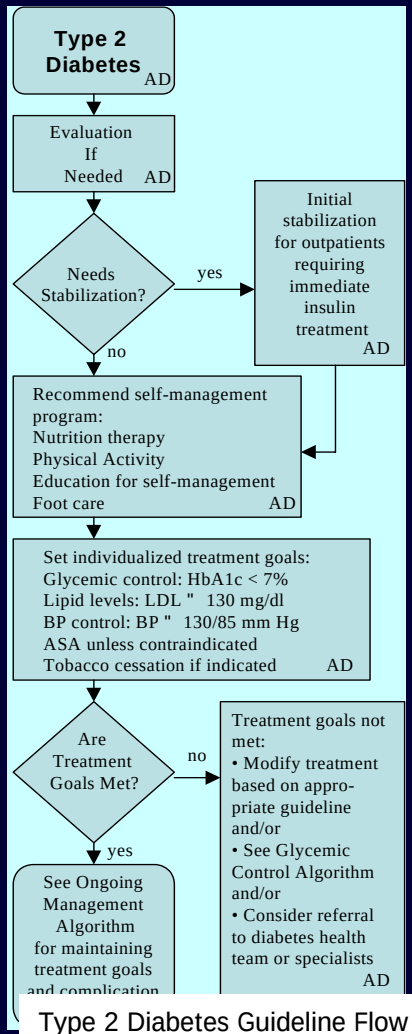


SAGE Main deliverables

- An interoperable guideline model – A computable knowledge representation "format" for encoding the content and logic of executable clinical practice guidelines.
- A guideline workbench – A software tool for authoring, encoding, and maintaining guidelines in the format of the SAGE guideline model.
- A guideline deployment system – Software that "decodes" the content of electronic guidelines and surfaces that content via functions of the local clinical information system.
- Controlled resources -- Specification of a common layer of information models and terminologies to mediate guideline content.

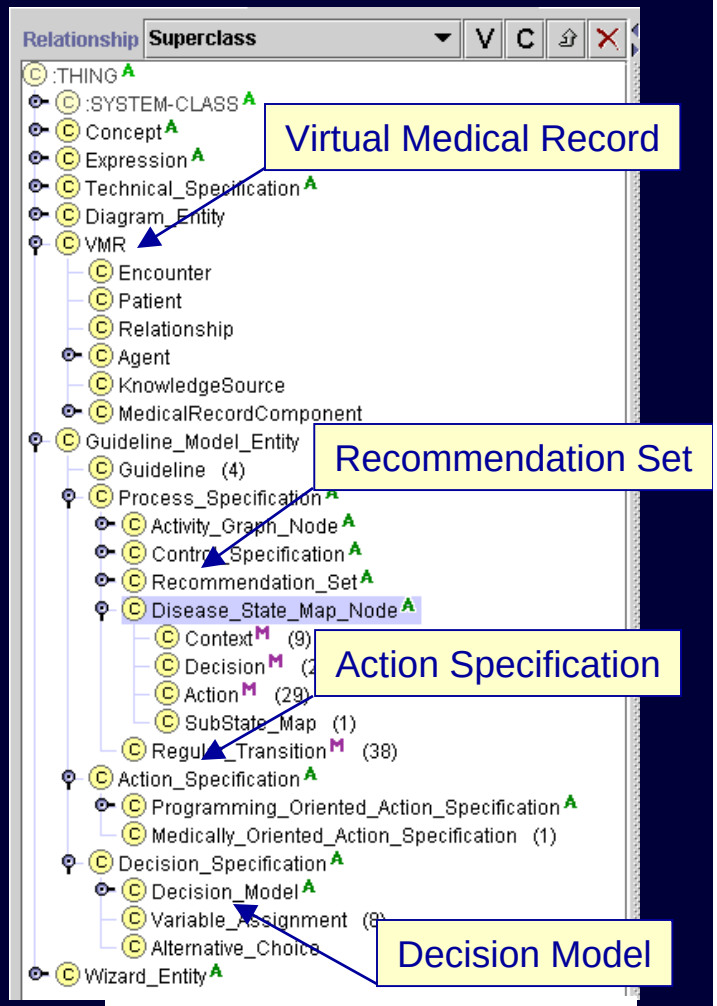
SAGE Interoperable Guideline Model

A standard computable "specification" for representing and encoding the content and logic of clinical practice guidelines



Type 2 Diabetes Guideline Flow Diagram, courtesy of Institute for Clinical Systems Improvement (ICSI)

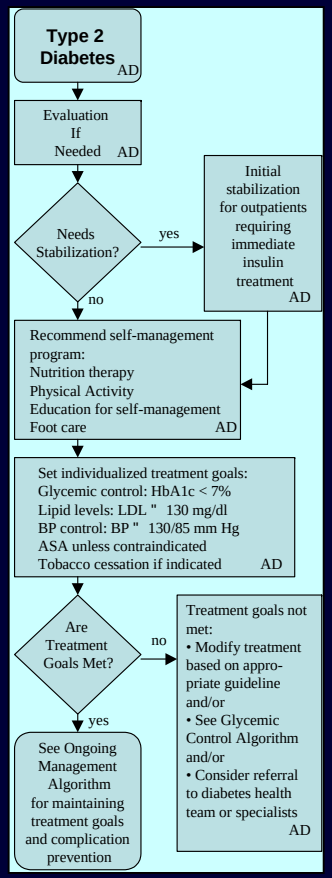
- ✓ Clinical content (criteria, actions)
- ✓ Patient status and eligibility
- ✓ Decision logic
- ✓ Clinical sequencing and workflow
- ✓ Guideline goals and intentions
- ✓ Guideline evidence and references

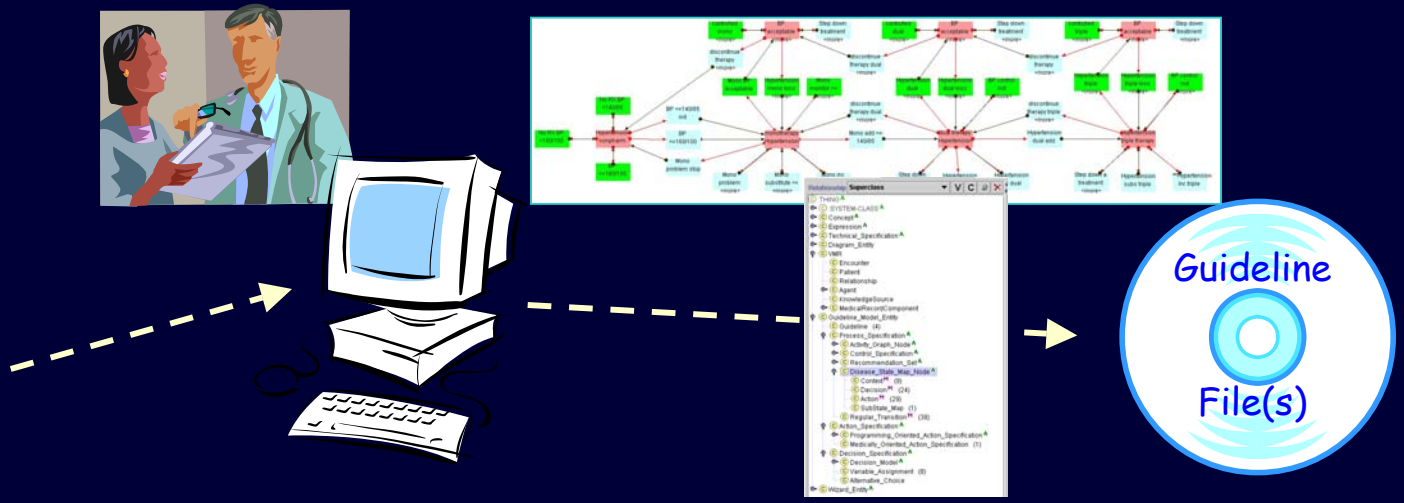


Protégé Guideline Model Knowledge Base, Courtesy Stanford Medical Informatics

Interoperable Guideline Workbench

A software tool for authoring, editing, encoding, and maintaining guidelines in the format of the Guideline Model



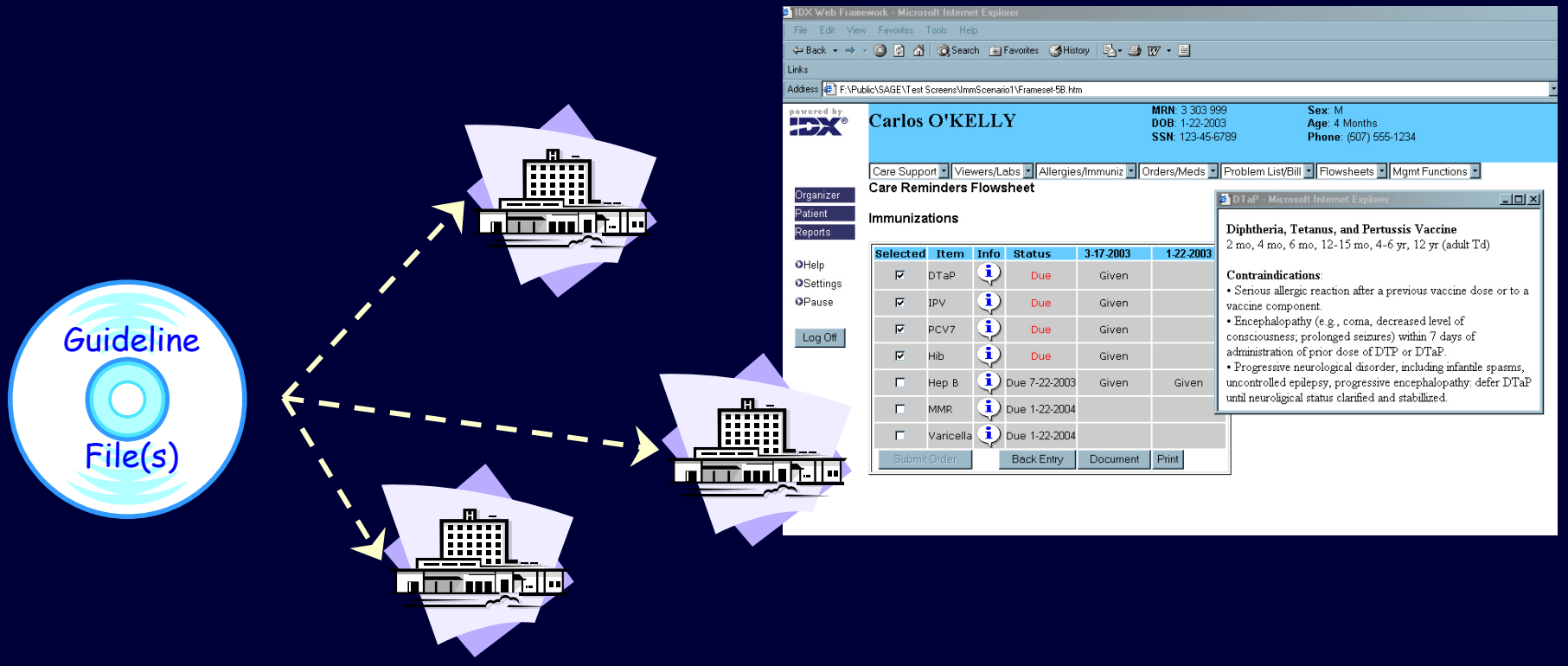


- ✓ Ensure complete ***encoding*** of guideline knowledge
- ✓ Support access to guideline content model
- ✓ Support access to controlled terminologies
- ✓ Support for visualization of guideline logic

Guideline Deployment System

Software that integrates electronic guidelines with the clinical information system to operationalize the guideline for clinicians

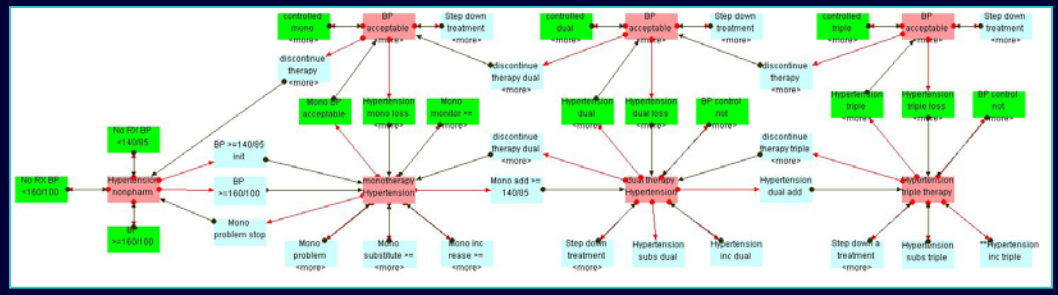
- ✓ Administer: Download, import, store
- ✓ Localize: Clinical edits, local constraints
- ✓ Set Up: Mapping to local terminologies and EMR
- ✓ Execute: Activation of guideline via CIS workflow



Specification of Standards

A common “layer” of terminology and information models that mediates guideline encoding and execution.

- ✓ Adoption of standard terminologies (e.g., LOINC, SNOMED CT)
- ✓ Specification of standard information models (e.g., for patient data).
- ✓ Specification of a standard for guideline knowledge representation.
- ✓ Employment of a standard expression language for guideline logic.



SAGE Exemplar Guidelines

Guideline	Clinical Domain
Immunizations	Routine health maintenance, in both outpatient and inpatient settings.
Diabetes Management	Chronic disease monitoring and treatment. Acute exacerbation of chronic disease. Chronic disease as a cormorbidity.
Community Acquired Pneumonia	Emergency room evaluation and diagnosis. Outpatient treatment of acute disease. Inpatient and ICU treatment of acute disease. Follow-up of acute disease.

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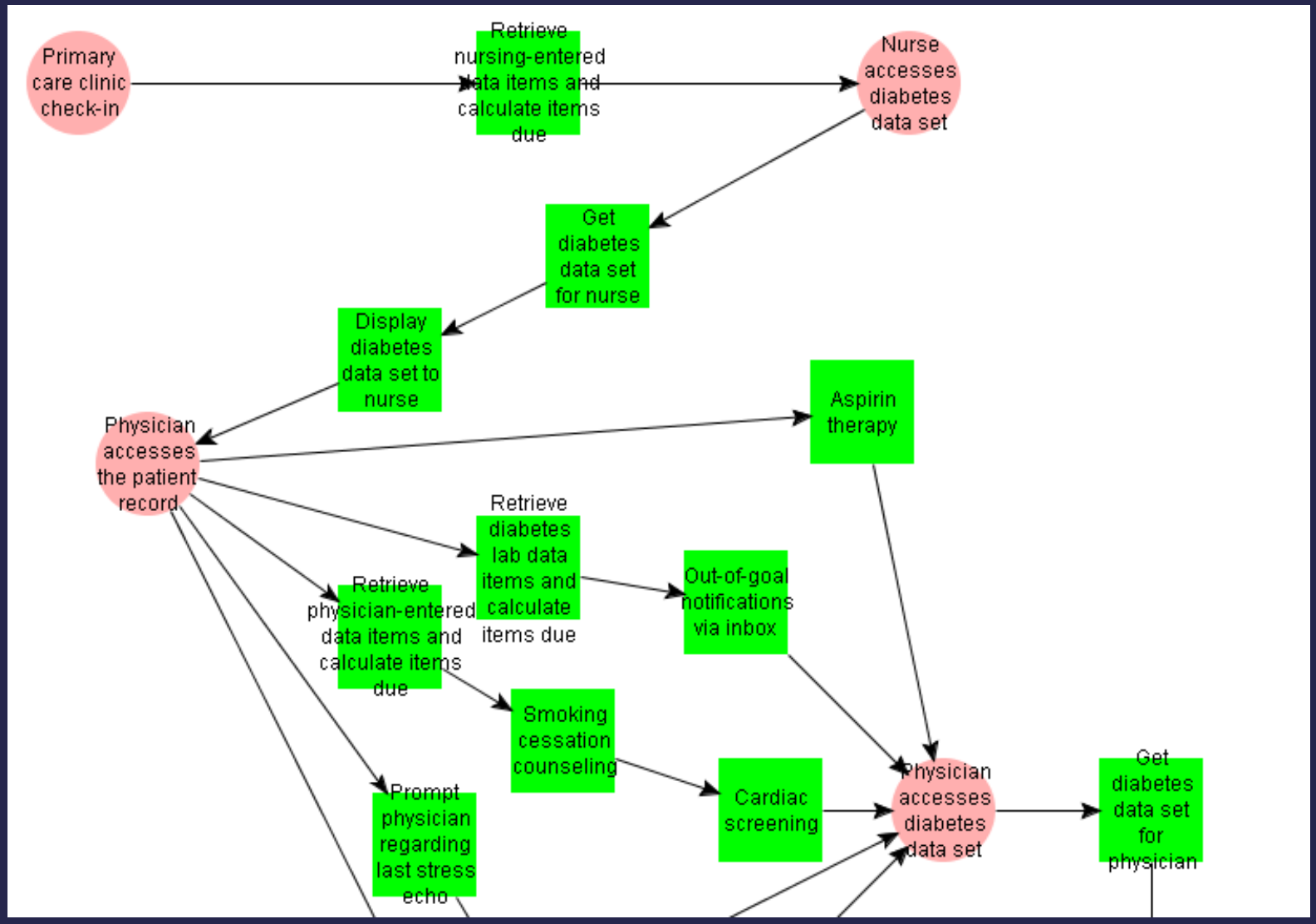
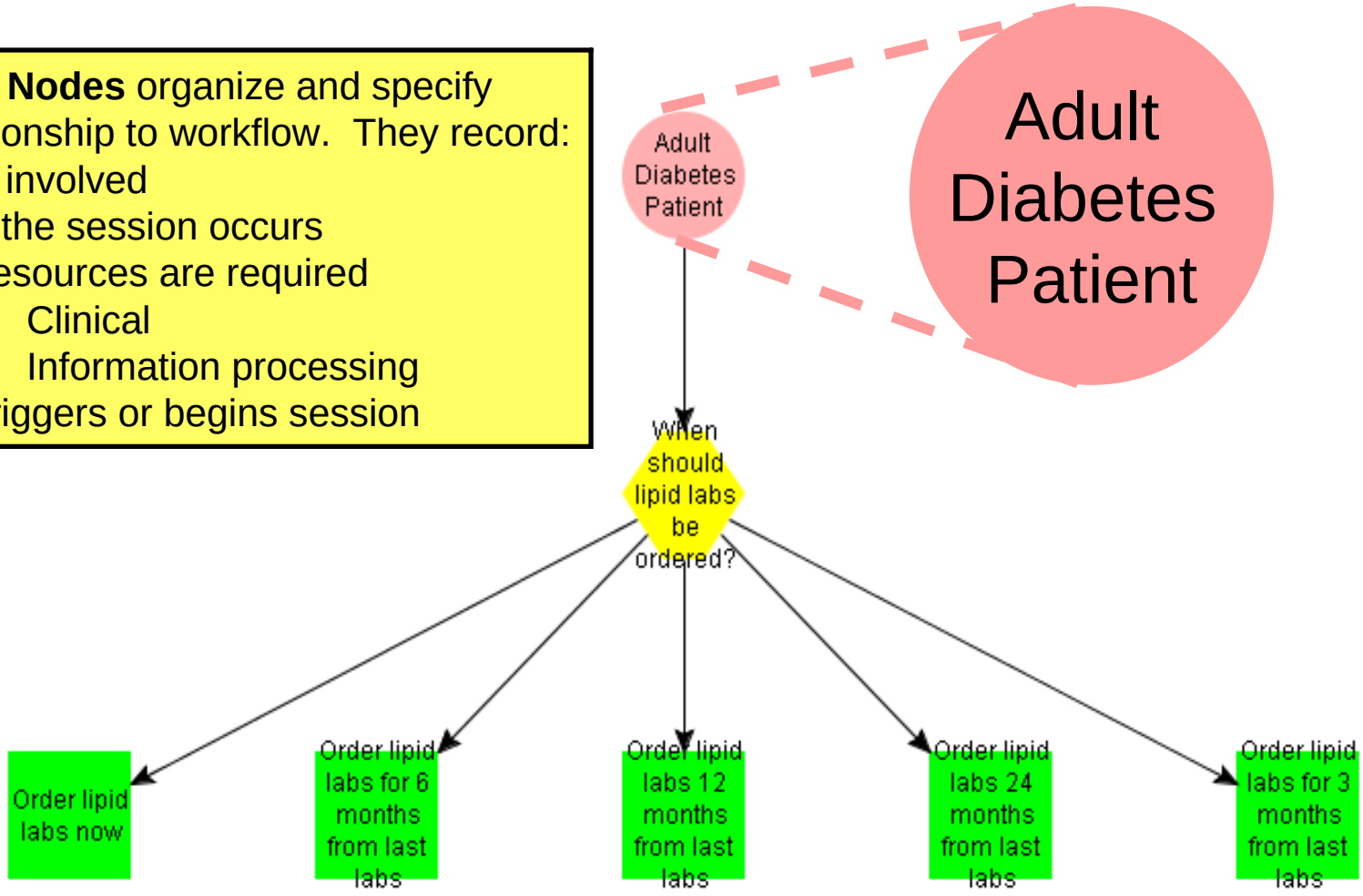
Sample Activity Graph:
Diabetes Primary Care



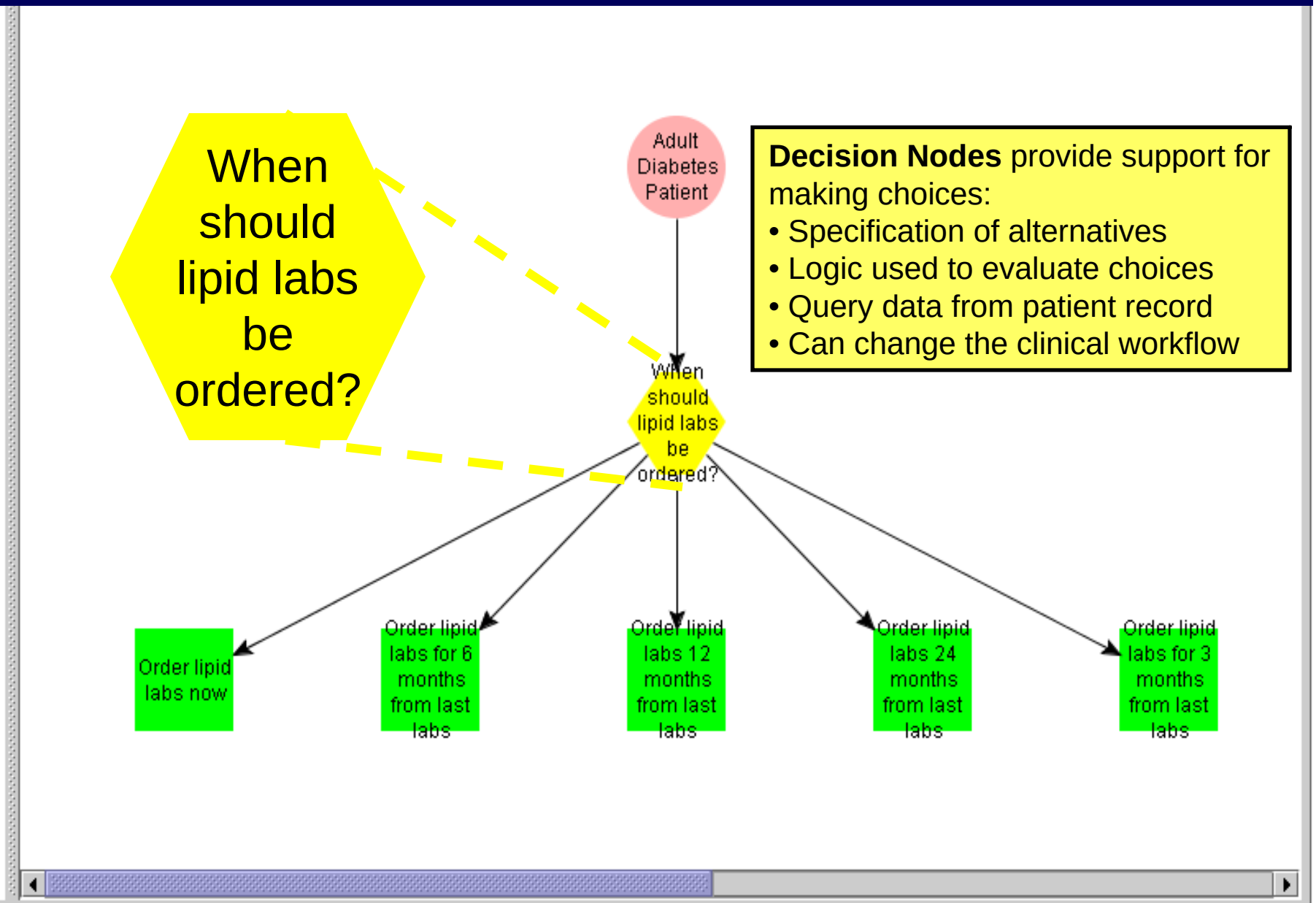
SAGE Guideline Representation: Context Nodes

Context Nodes organize and specify the relationship to workflow. They record:

- Who is involved
- Where the session occurs
- What resources are required
  - Clinical
  - Information processing
- What triggers or begins session



SAGE Guideline Representation: Decision Nodes



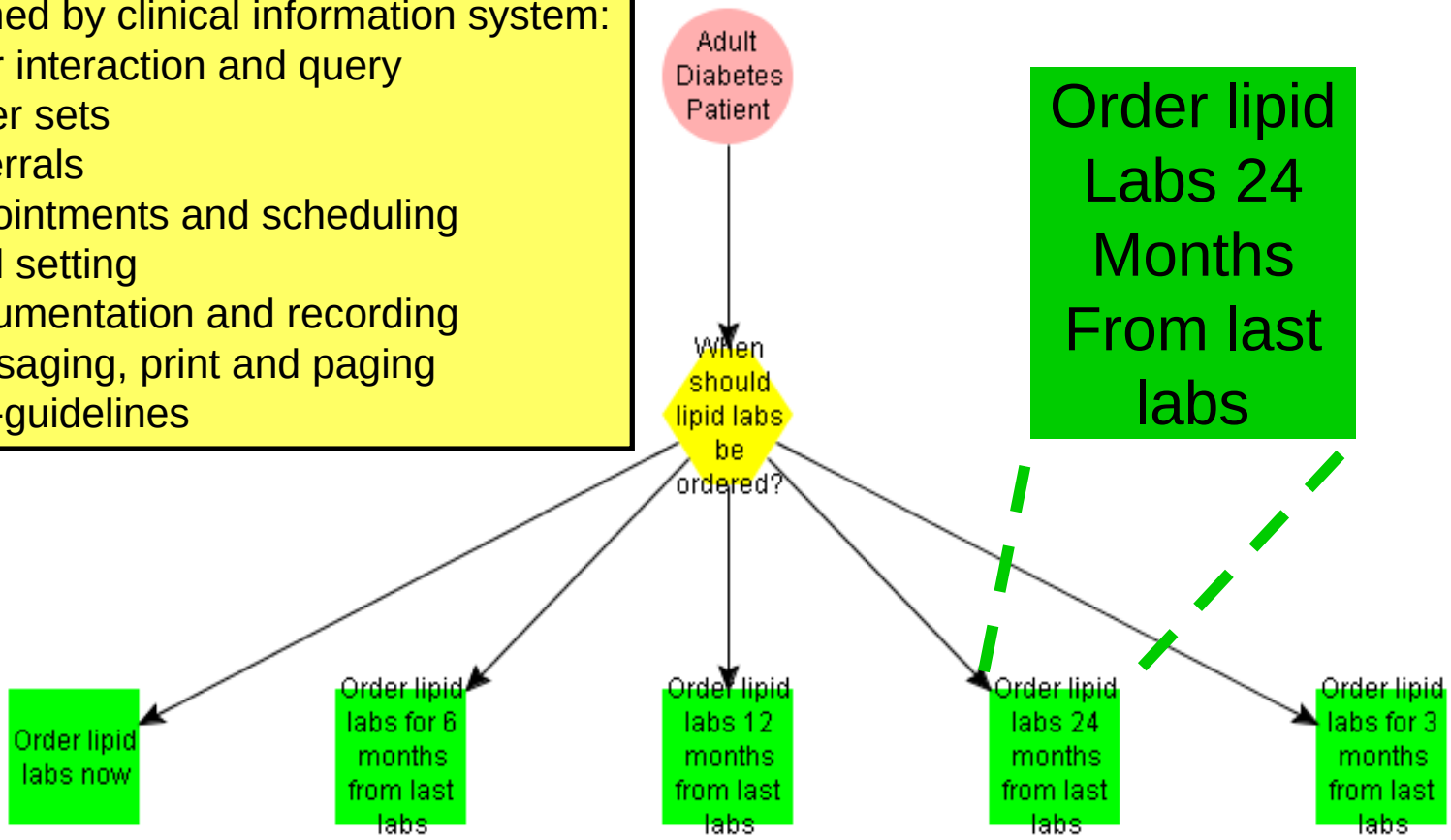
Decision Nodes provide support for making choices:

- Specification of alternatives
- Logic used to evaluate choices
- Query data from patient record
- Can change the clinical workflow

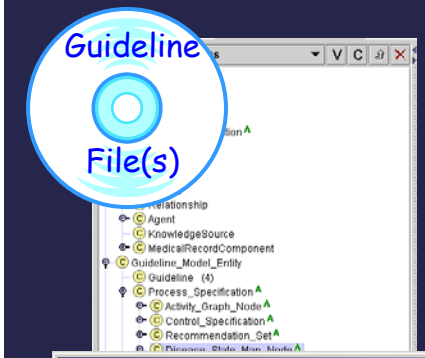
SAGE Guideline Representation: Action Nodes

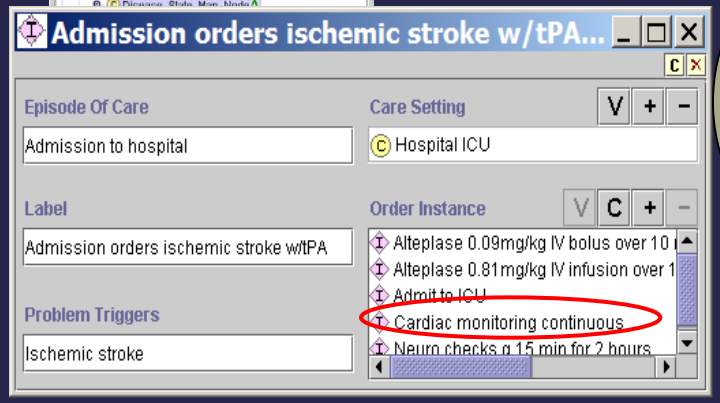
Action Nodes define activity to be accomplished by clinical information system:

- User interaction and query
- Order sets
- Referrals
- Appointments and scheduling
- Goal setting
- Documentation and recording
- Messaging, print and paging
- Sub-guidelines



SAGE Guideline Execution:
Deployment Concepts





Local
Clinical Information System

SAGE
Guideline
Engine

Queries

EMR Data

Patient
Record

Events

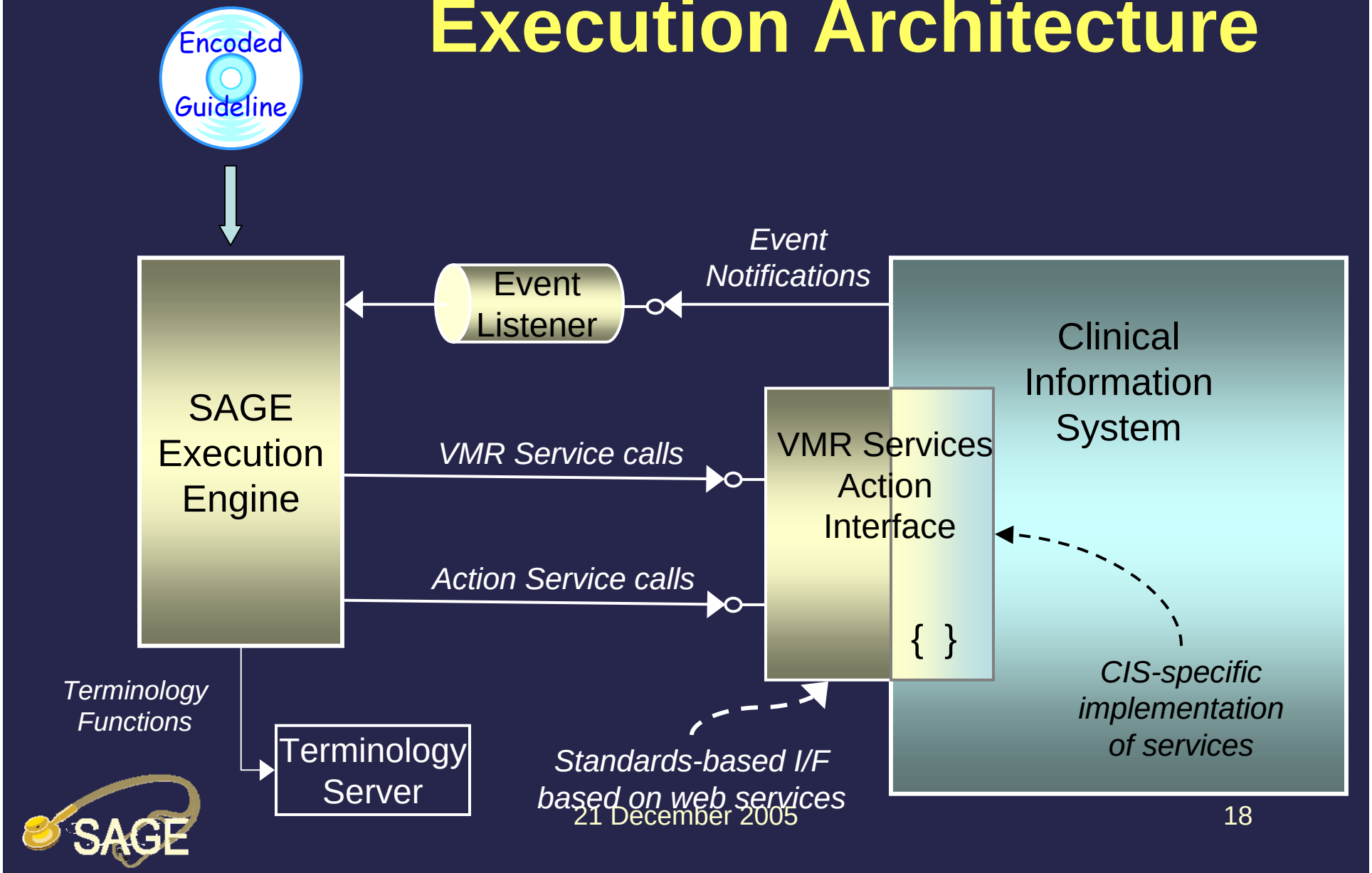
Execution
System

Actions

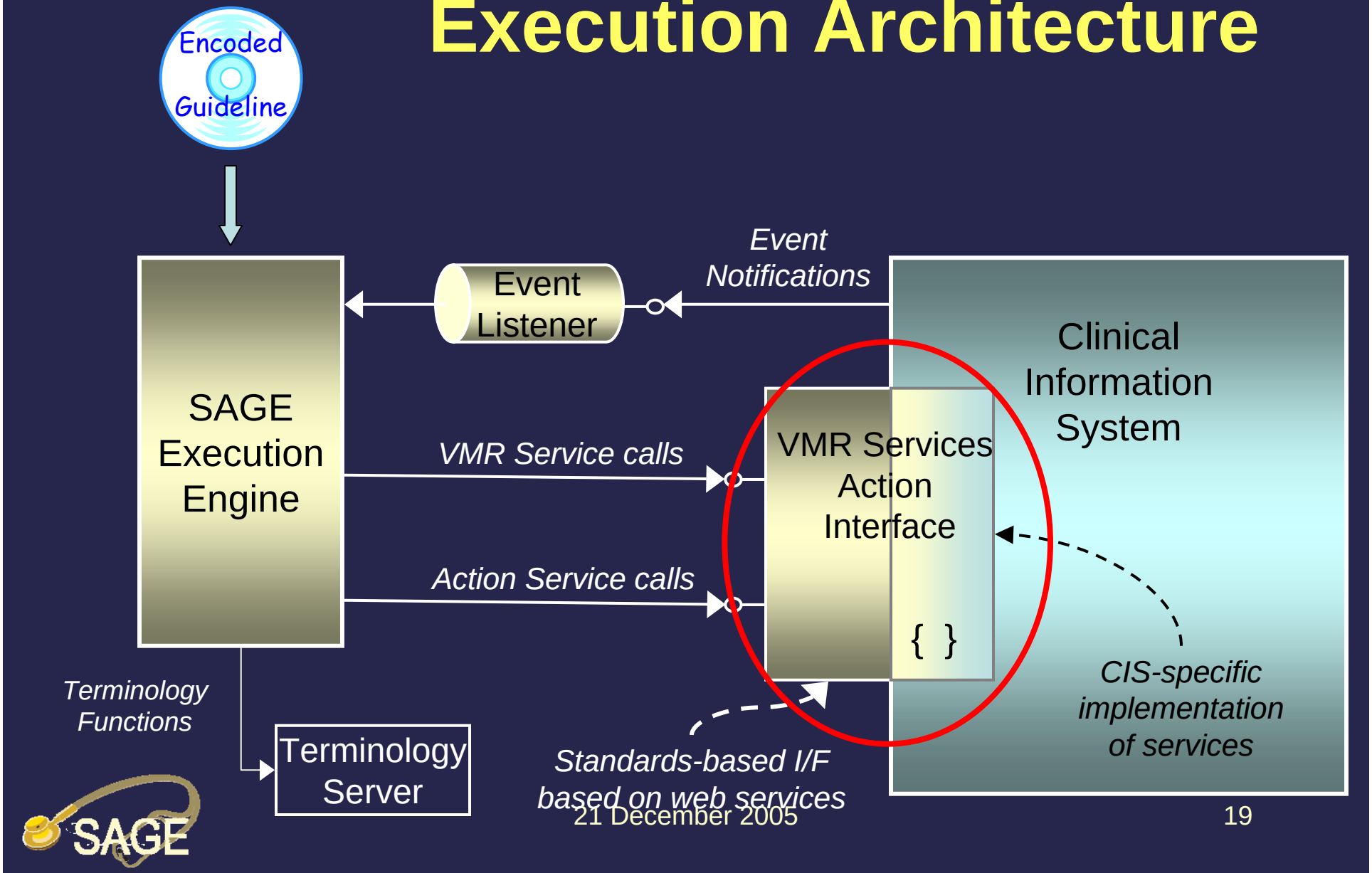
Order
Entry

Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.

SAGE Guideline Execution Architecture

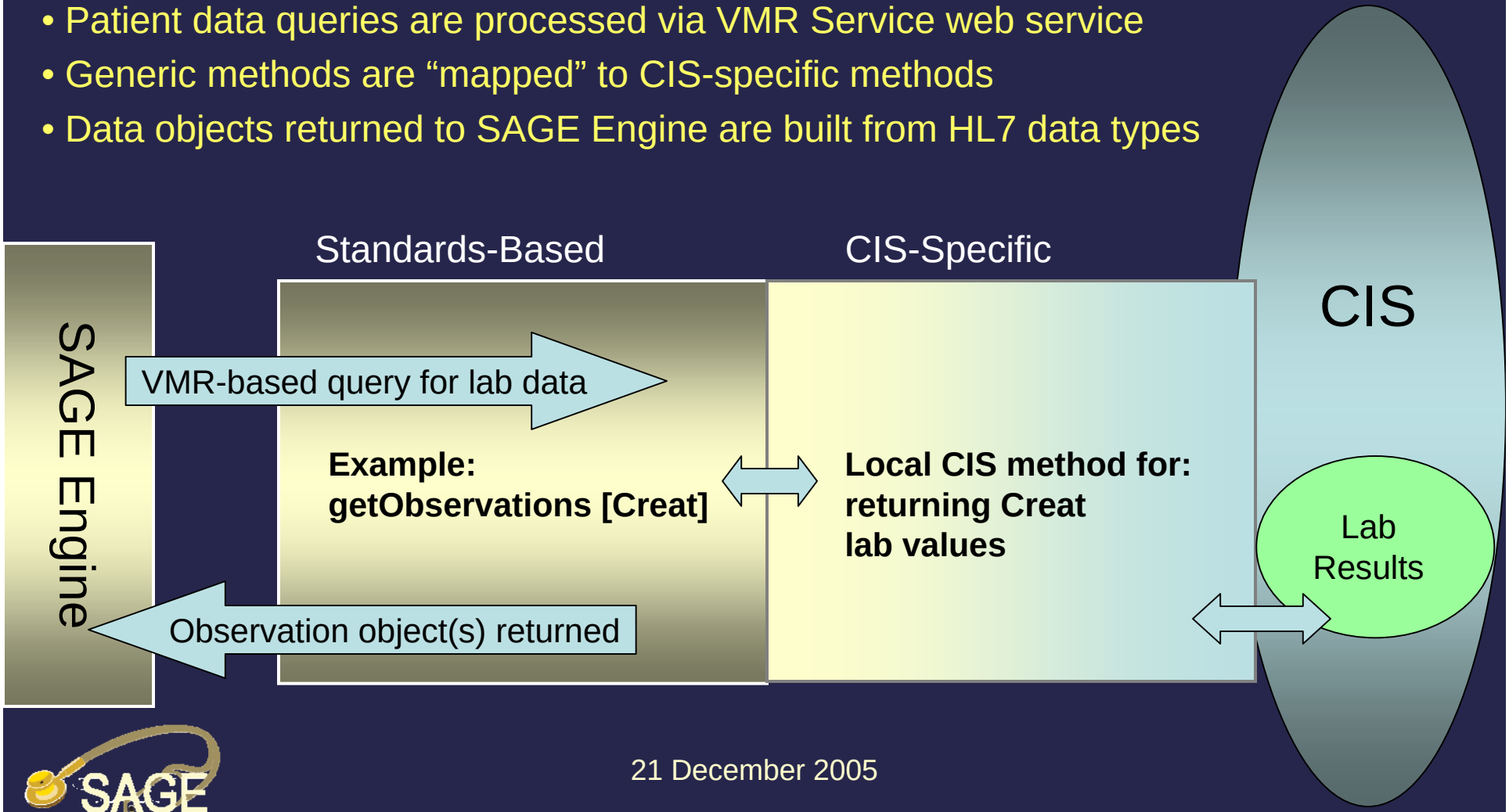


SAGE Guideline Execution Architecture

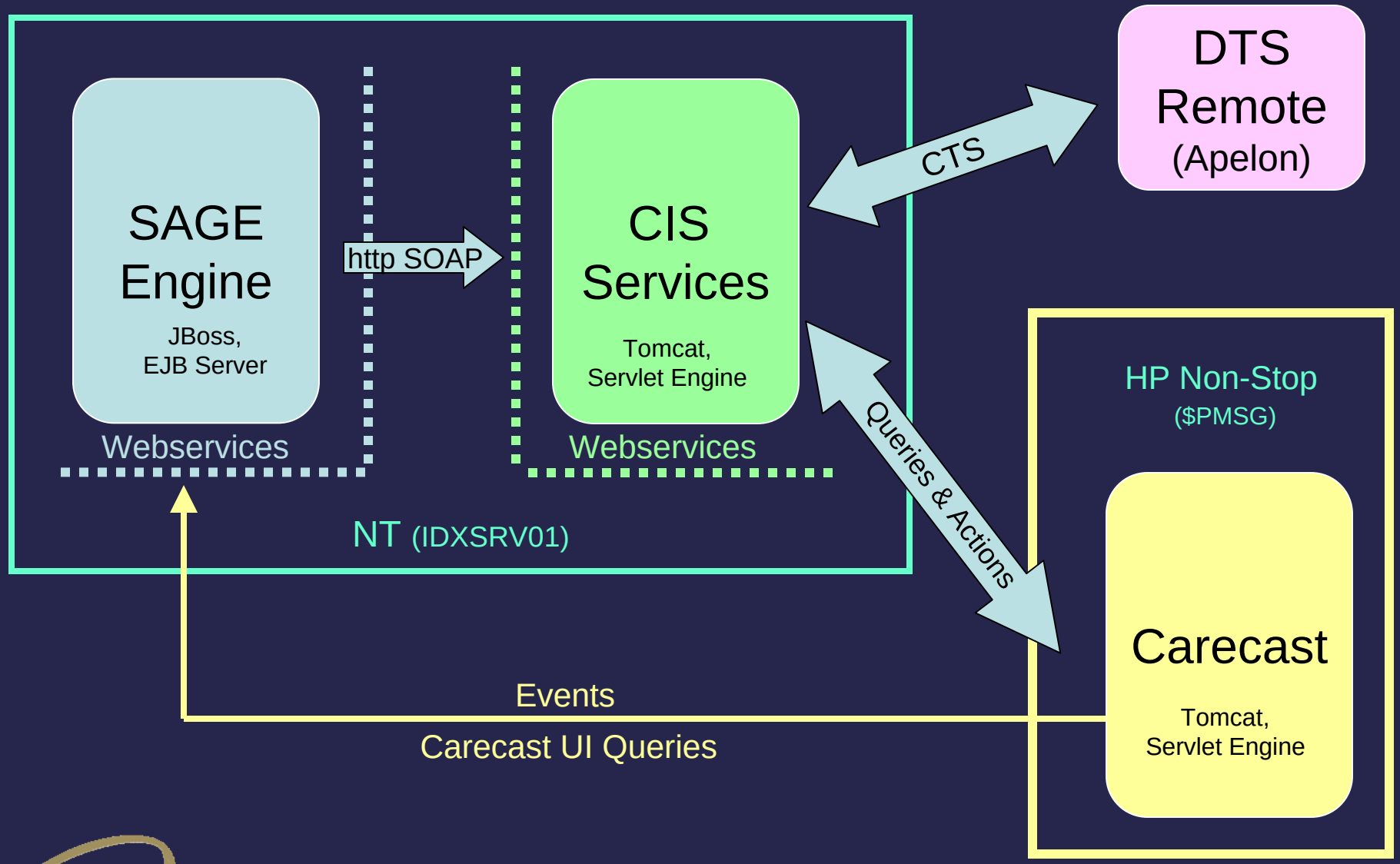


VMR Services Interface

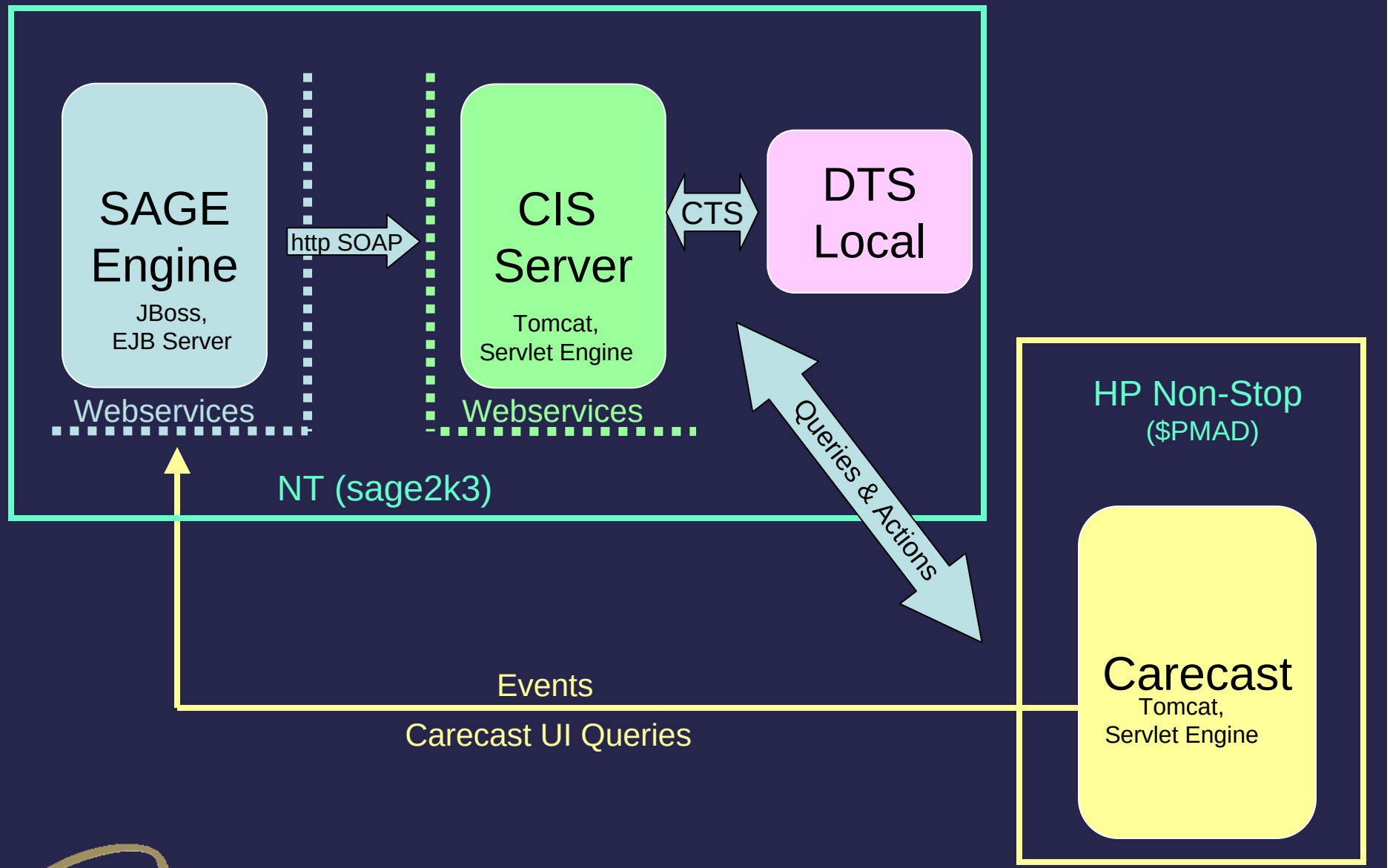
- In the guideline model, patient data concepts are represented using VMR classes
- Queries for patient data are represented using standard VMR-based methods
- Patient data queries are processed via VMR Service web service
- Generic methods are “mapped” to CIS-specific methods
- Data objects returned to SAGE Engine are built from HL7 data types



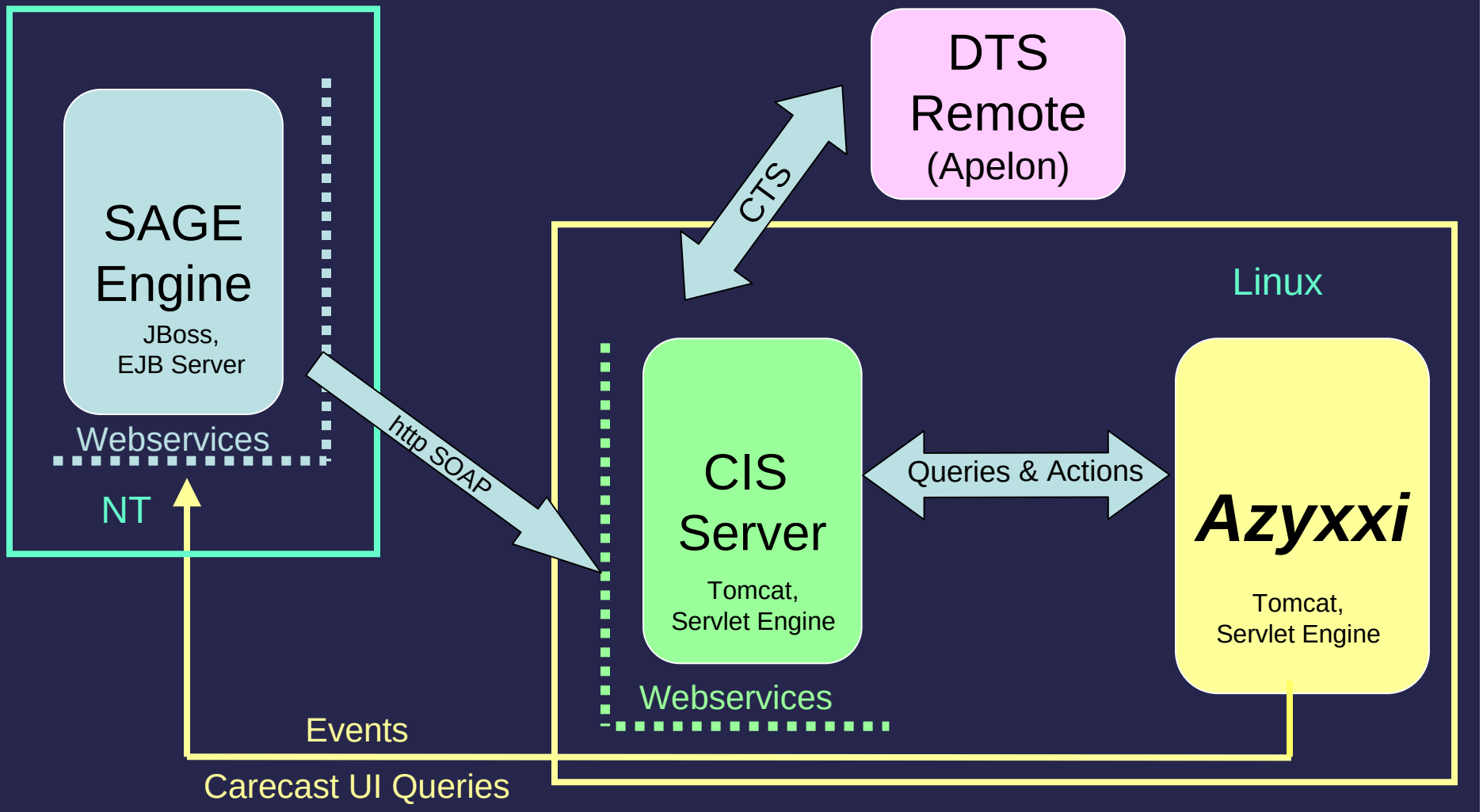
Implementation Architecture at Mayo



Seattle Implementation Architecture

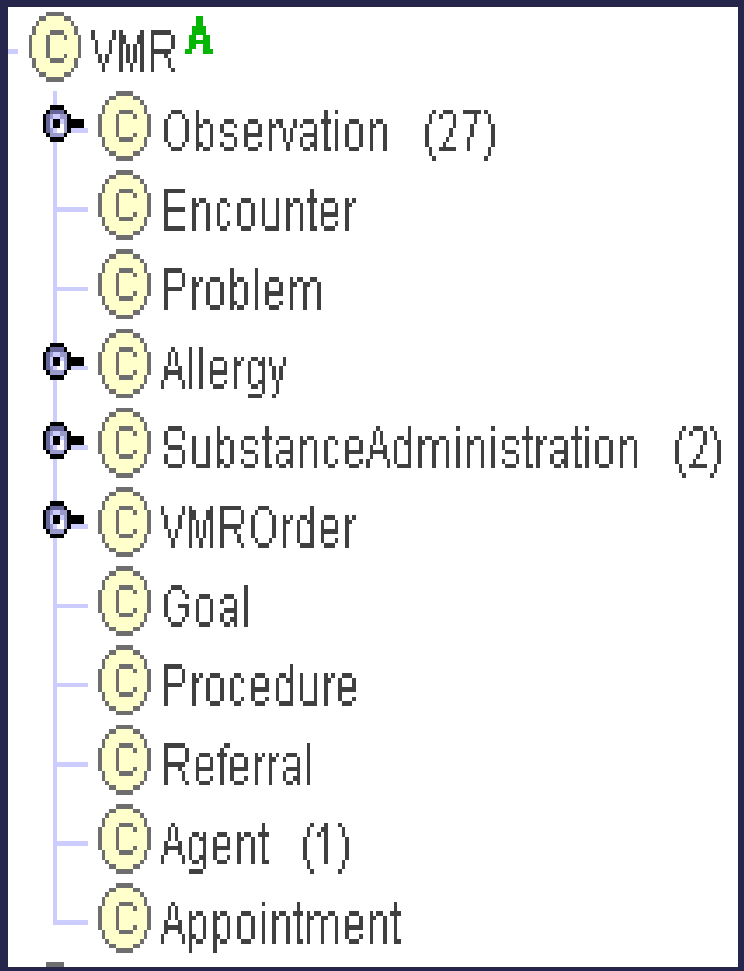


Alternative Implementation Architecture



The Virtual Medical record

- Protégé classes "define" services through which SAGE communicates with the CIS
- Attributes of these vMR classes control the ways requests are modeled in the guideline and, thus, the way that calls to the CIS are composed.



SAGE requests Problems

```
Problem []        getProblems

  (
    CISContext              cisContext,
    String              medRecordNum,
    ProblemFilter           problemFilter
  )
```

SAGE requests Problems

```
Problem []        getProblems
  (
    CISContext          cisContext,
    String          medRecordNum,
    ProblemFilter       problemFilter
  )
```

user, passwd, sessionID

SAGE requests Problems

```
Problem []        getProblems
  (
    CISContext          cisContext,
    String              medRecordNum,
    ProblemFilter       problemFilter
  )
```

user, passwd, sessionID

patient

vmr

SAGE requests Problems

```
Problem []        getProblems
  (
    CISContext          cisContext,
    String              medRecordNum,
    ProblemFilter       problemFilter
  )
```

user, passwd, sessionID

patient

codes

SAGE gets Observations

```
Observation []   getObservations
   (
     CISContext              cisContext,
     String                  medRecordNum,
     ObservationFilter       observationFilter
   )
```

SAGE gets Observations

```
Observation []   getObservations
  (
    CISContext              cisContext,
    String                  medRecordNum,
    ObservationFilter       observationFilter
  )
```

codes, subtypes, etc.

The Problem Class

{

ConceptValue	code
TimeInterval	effectiveTime
String	status
ConceptValue	subject
String []	encounterIds

}

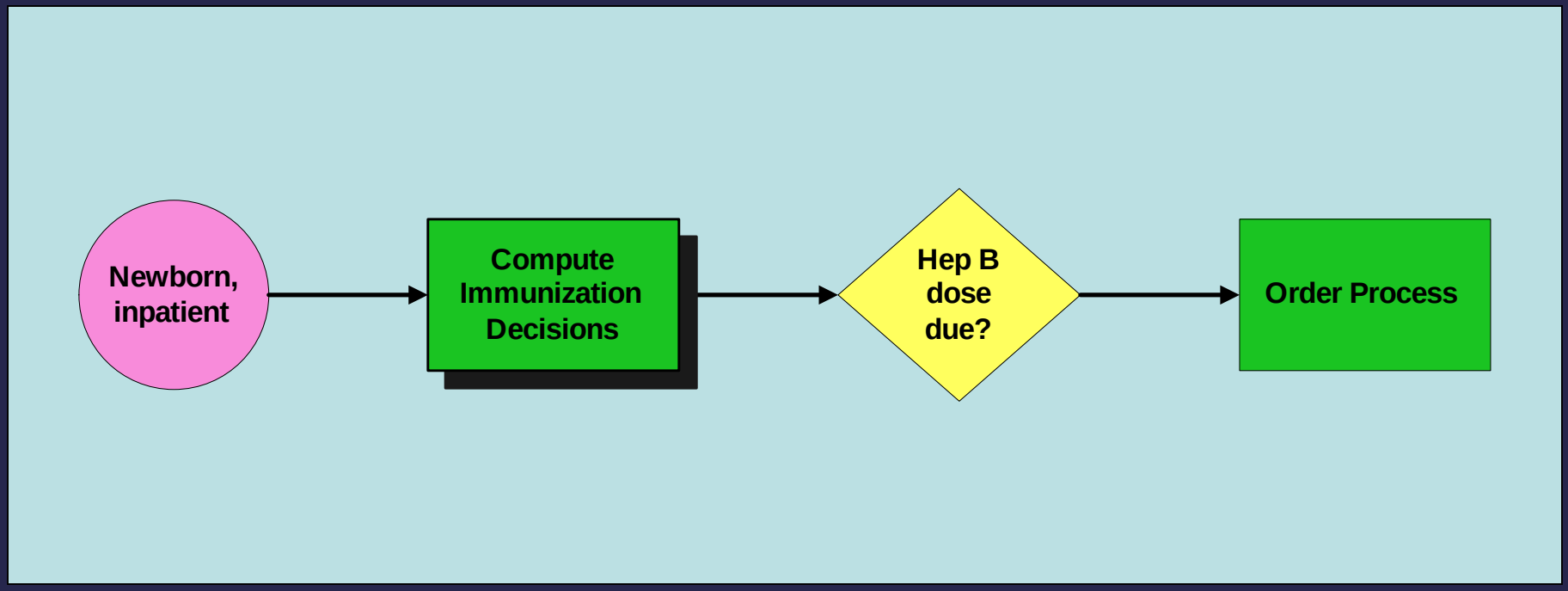
ConceptValue

```
{   String      conceptID
    String      name
    String      extra
    String      namespace
    String      version
    String      type
    boolean     subsumption   }
```

TimeInterval

```
{ java.util.Calendar    low
  java.util.Calendar    high   }
```

A Recommendation Set for Neonatal immunization orders…



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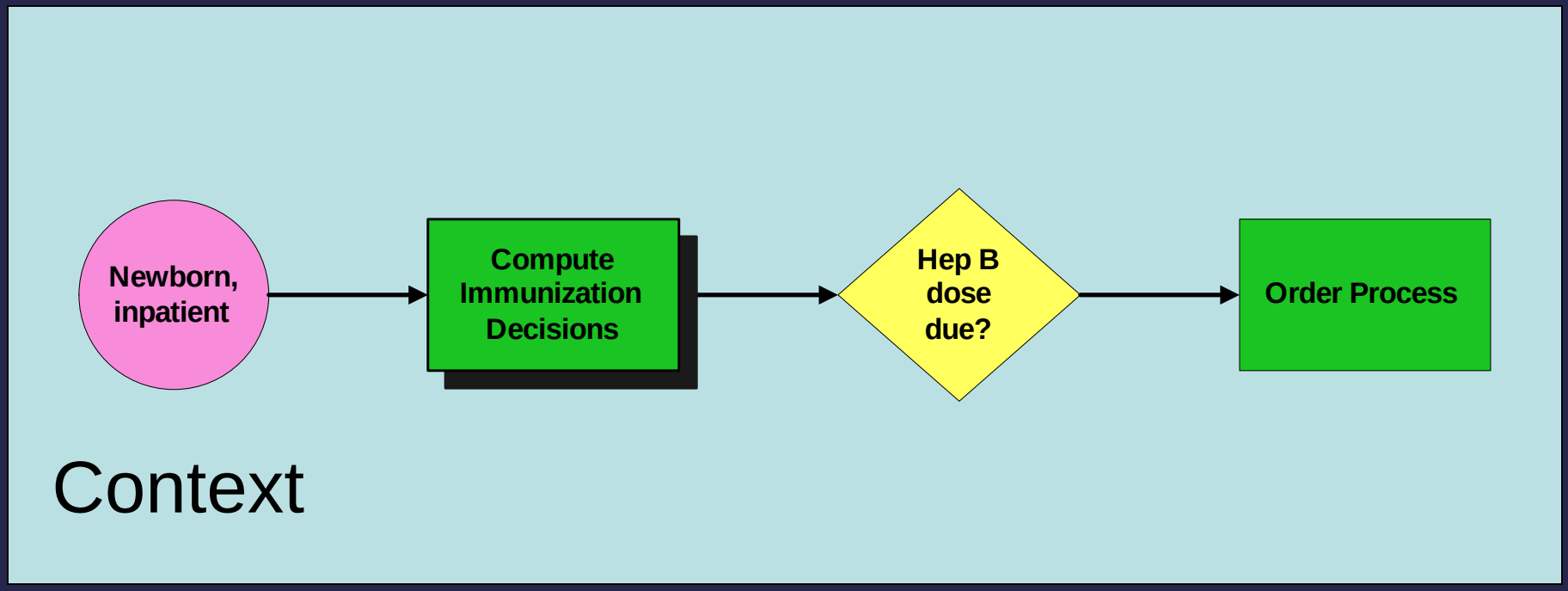

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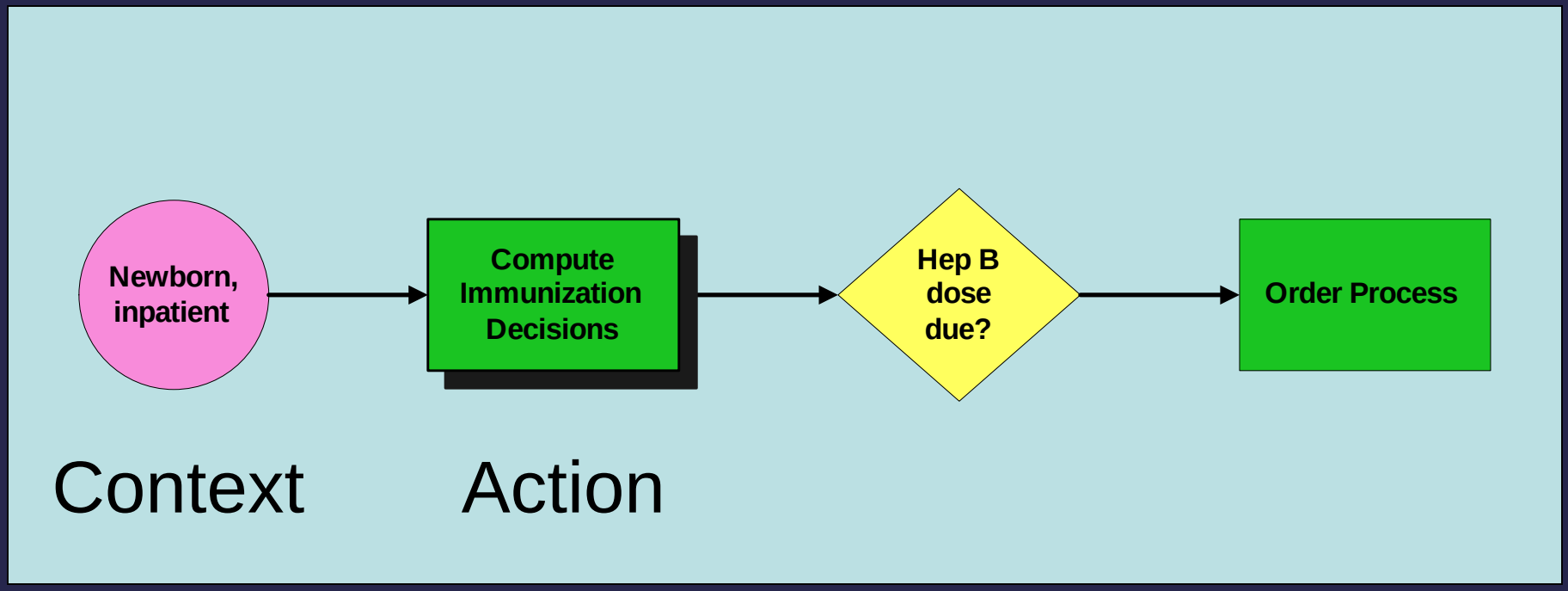
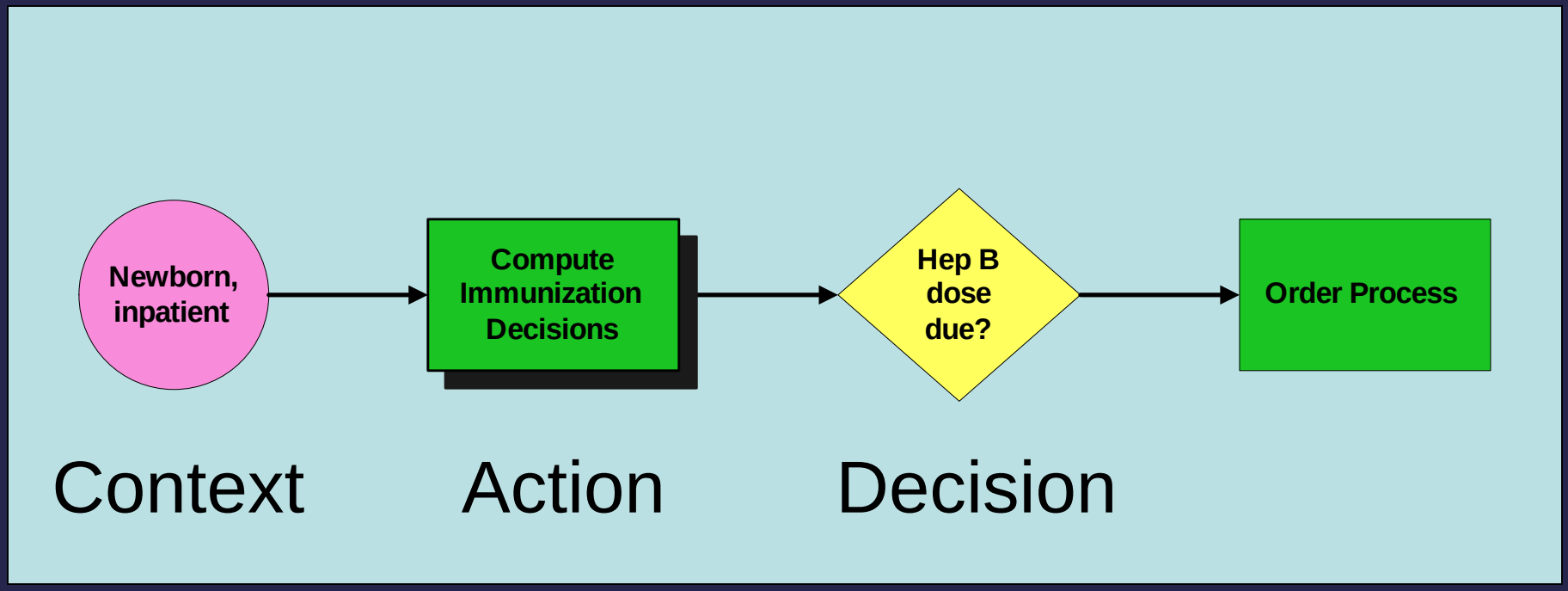
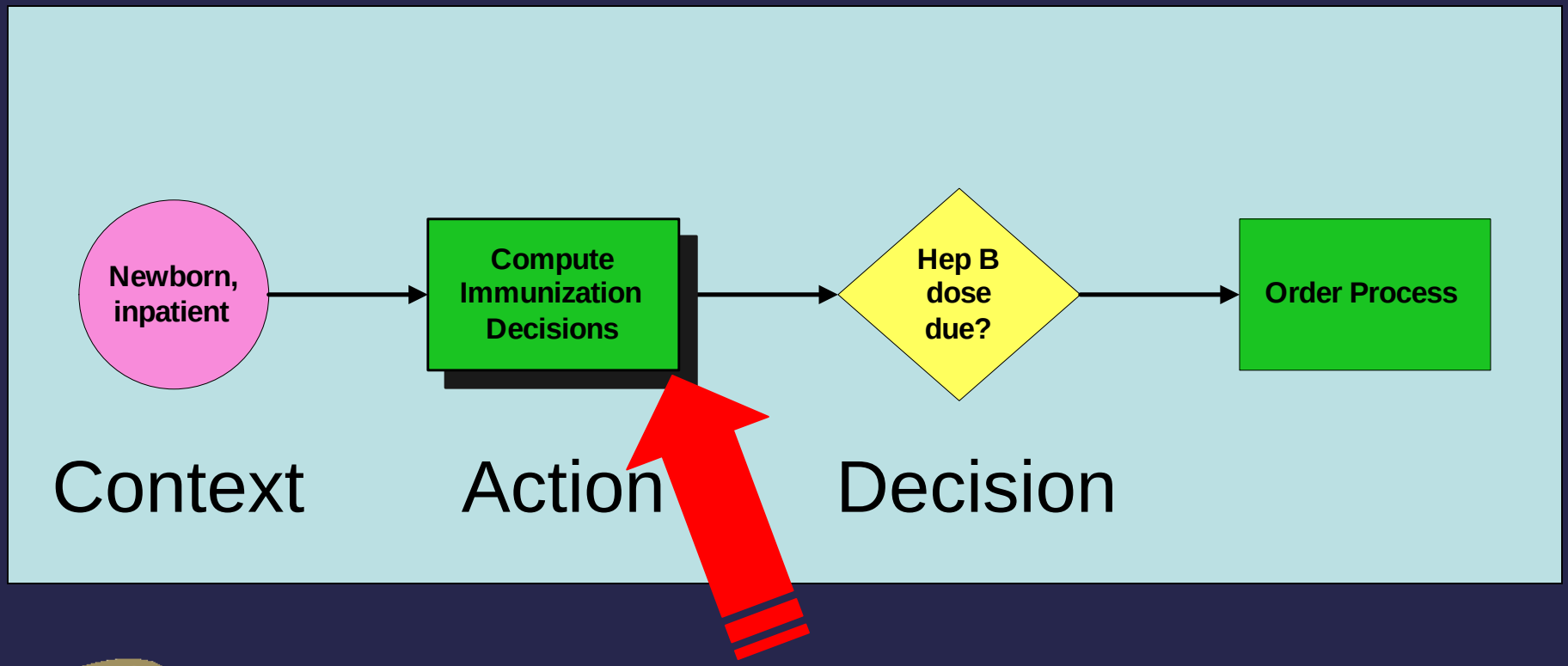
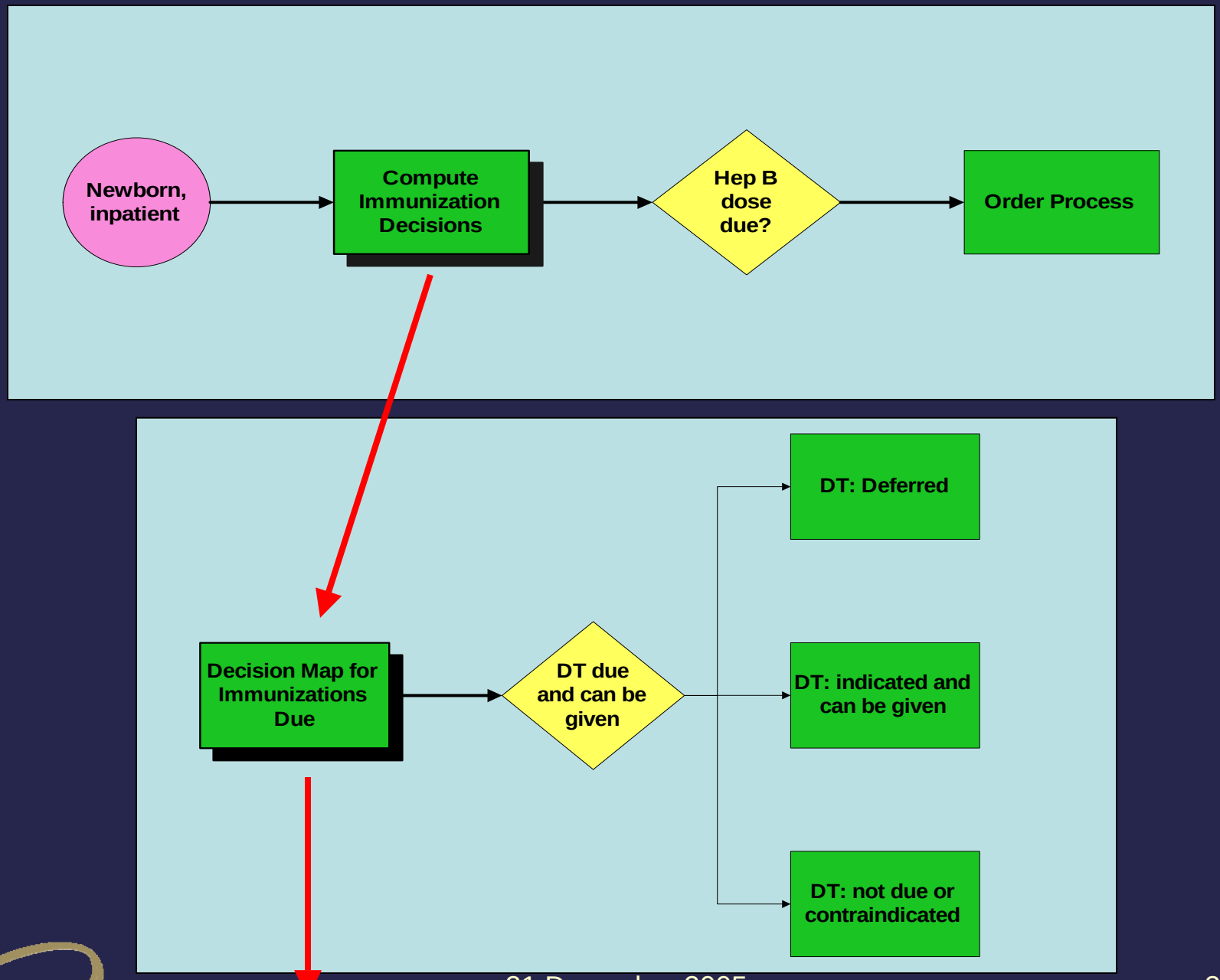


A Recommendation Set for Neonatal immunization orders…

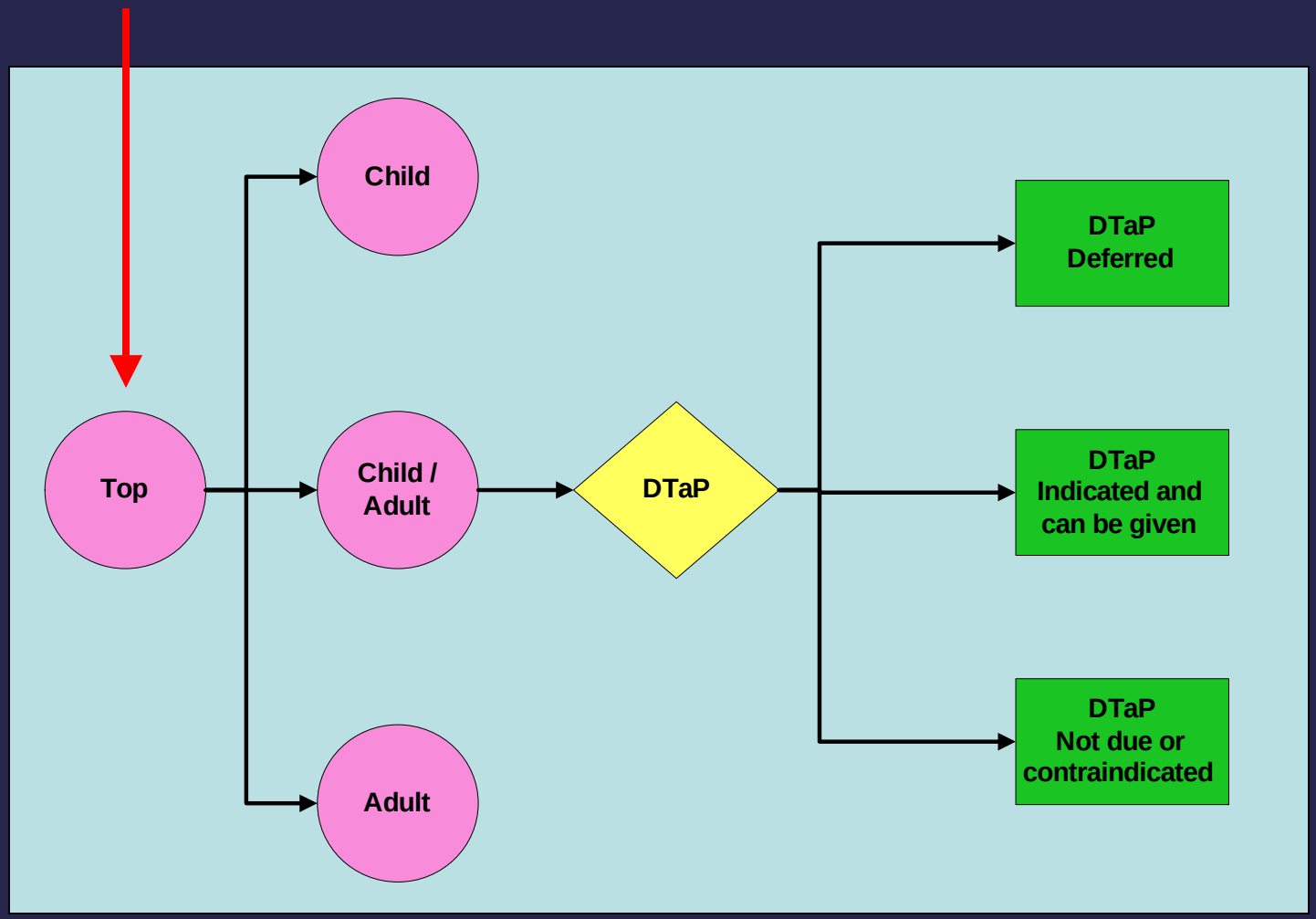


A Recommendation Set for Neonatal immunization orders…




Newborn, inpatient
Compute Immunization Decisions
Hep B dose due?
Order Process
Decision Map for Immunizations Due
DT due and can be given
DT: Deferred
DT: indicated and can be given
DT: not due or contraindicated

Immunization Decisions: DTaP



How does SAGE process criteria?

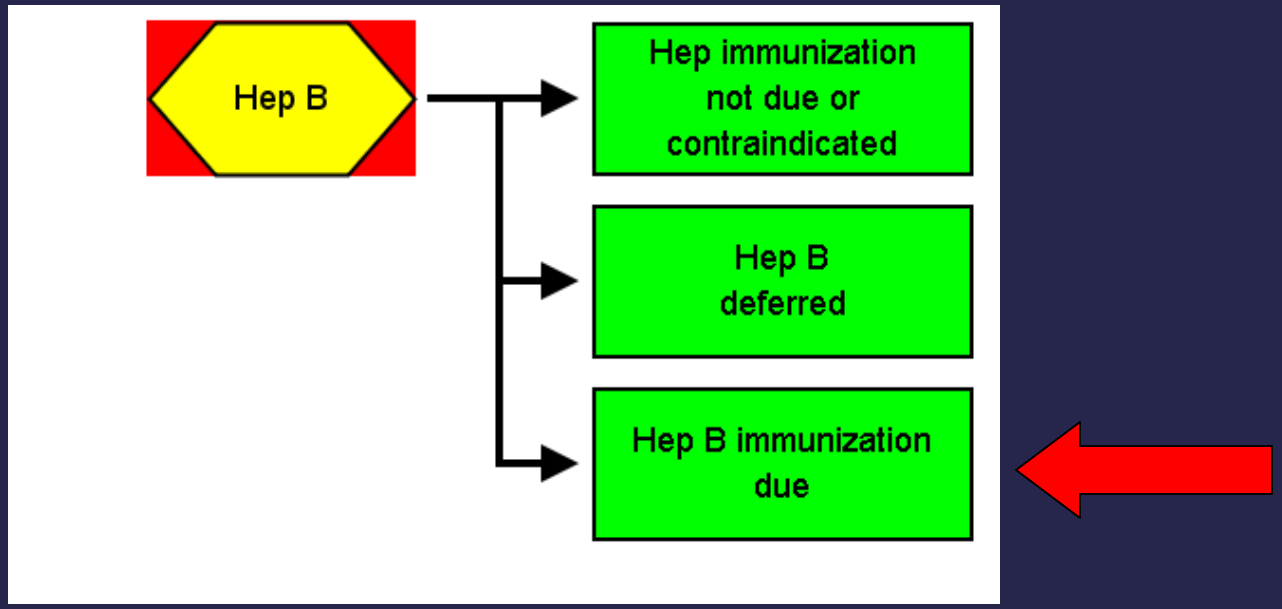
- Obtain CIS data (e.g., date of birth)
- Convert Units as required (e.g., lb to grams)
- Use evaluator for expressions
- Compute boolean (true or false)
- Examples:
  - » Age < 7 days
  - » Counting Previous Vaccinations
  - » Mother's HBsAG status
  - » Consent for Immunization

SAGE Execution

- Architecture
- Semantics of the guideline model
- Event driven interpretation
- Evaluation of criteria
- Example of decision making
- SAGE Actions

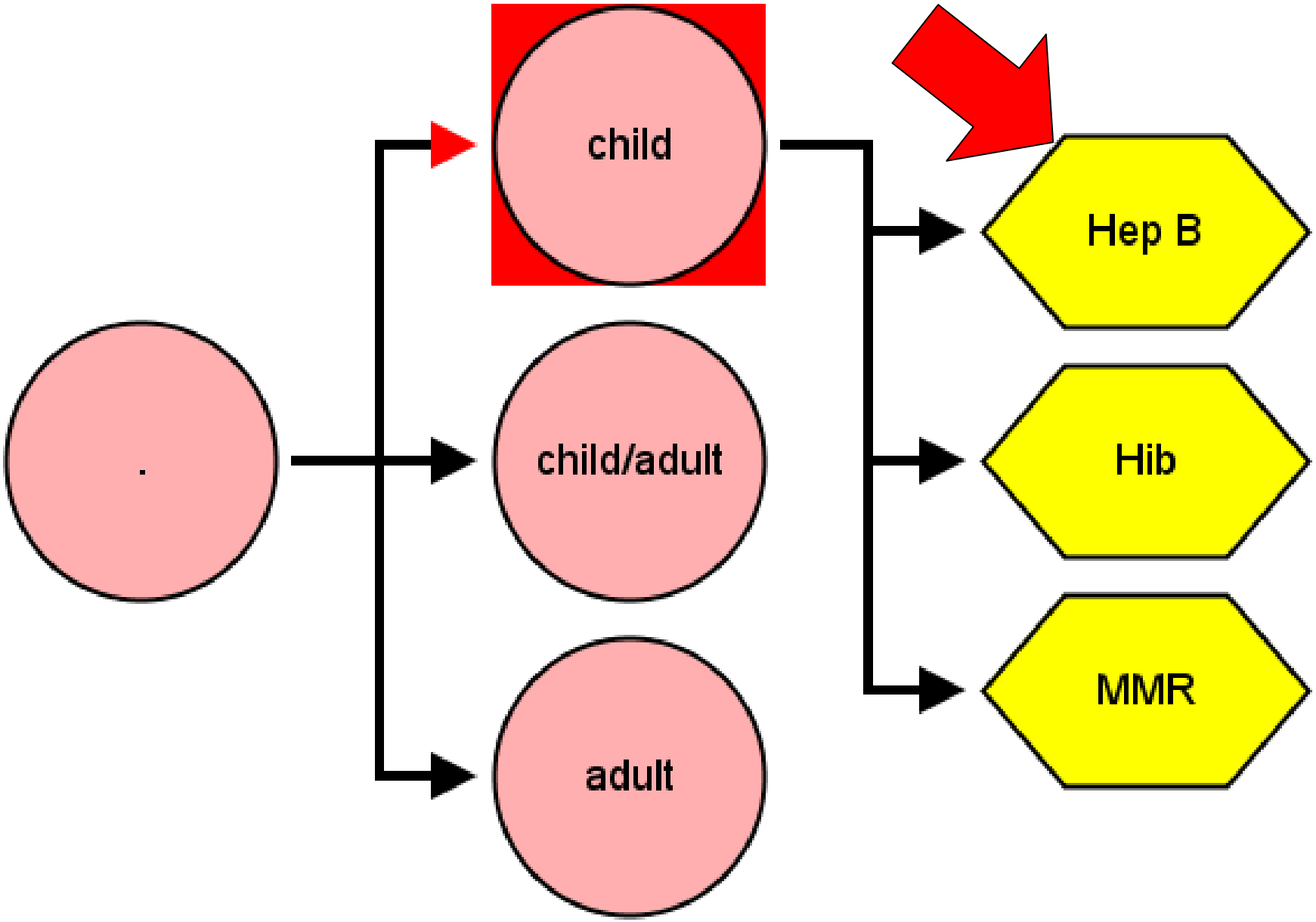
Decision Logic

Hep B vaccination is due.

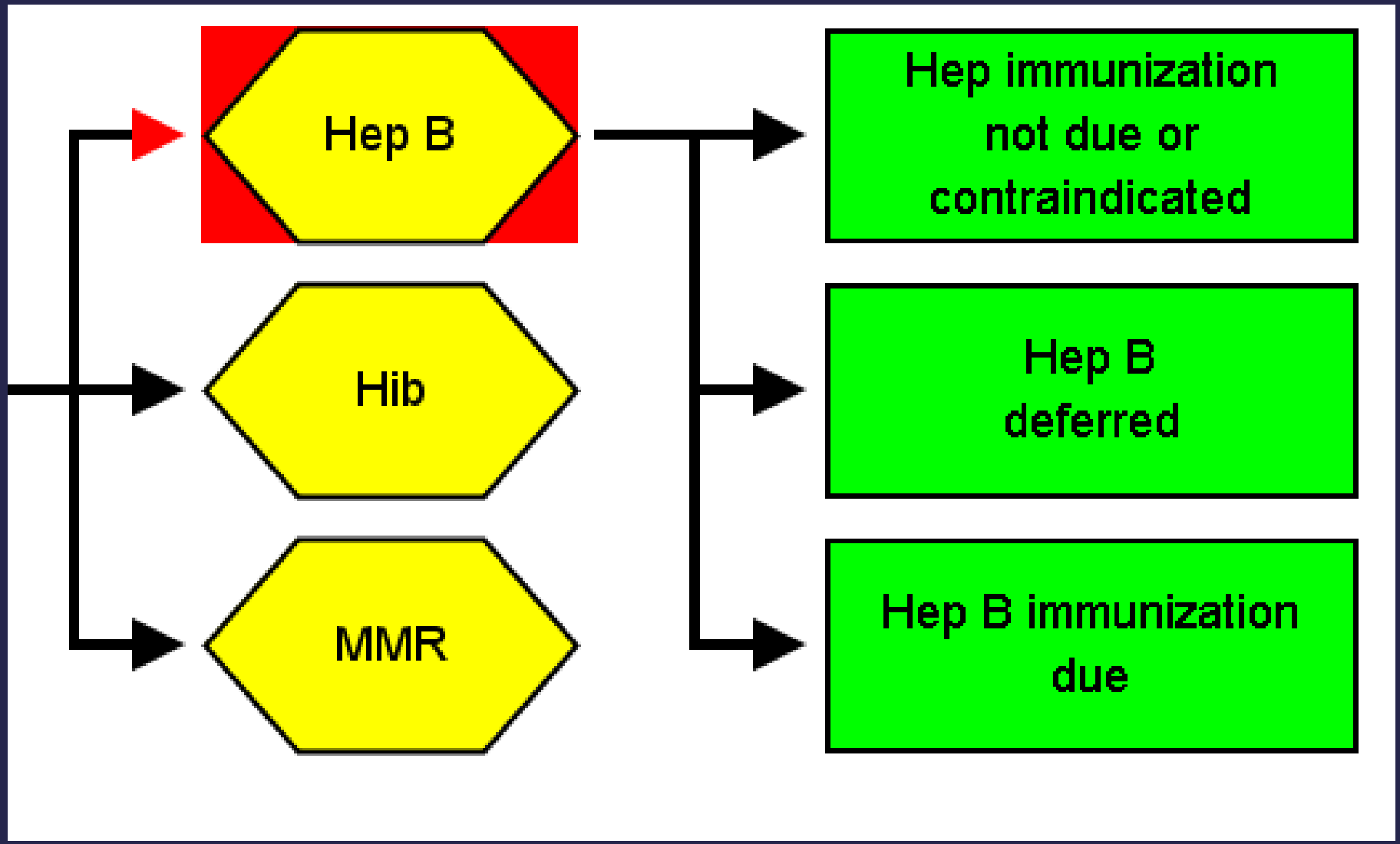


Next Prev Pause

Compute Immunizations / Decision Map



We have 3 possibilities.



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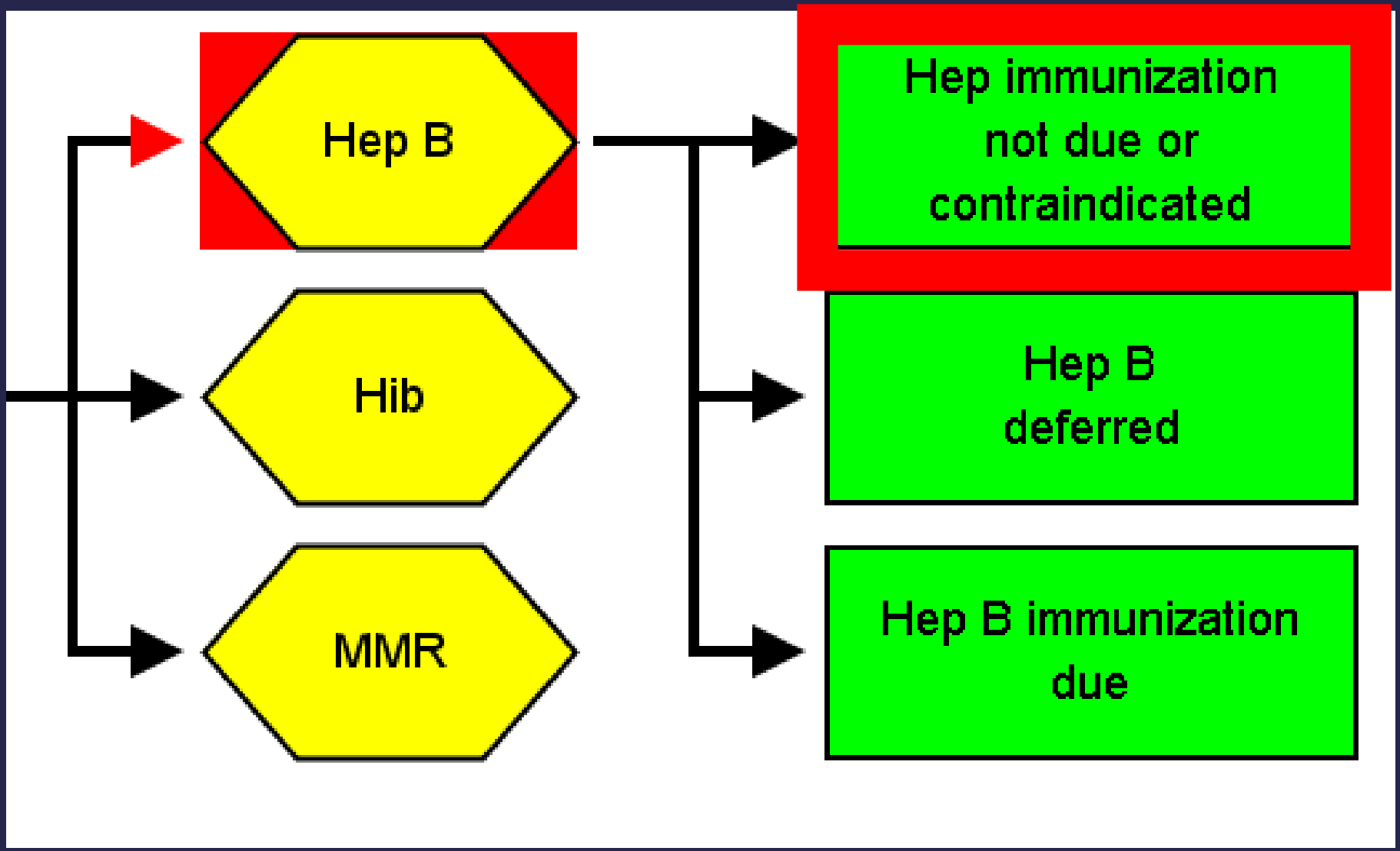

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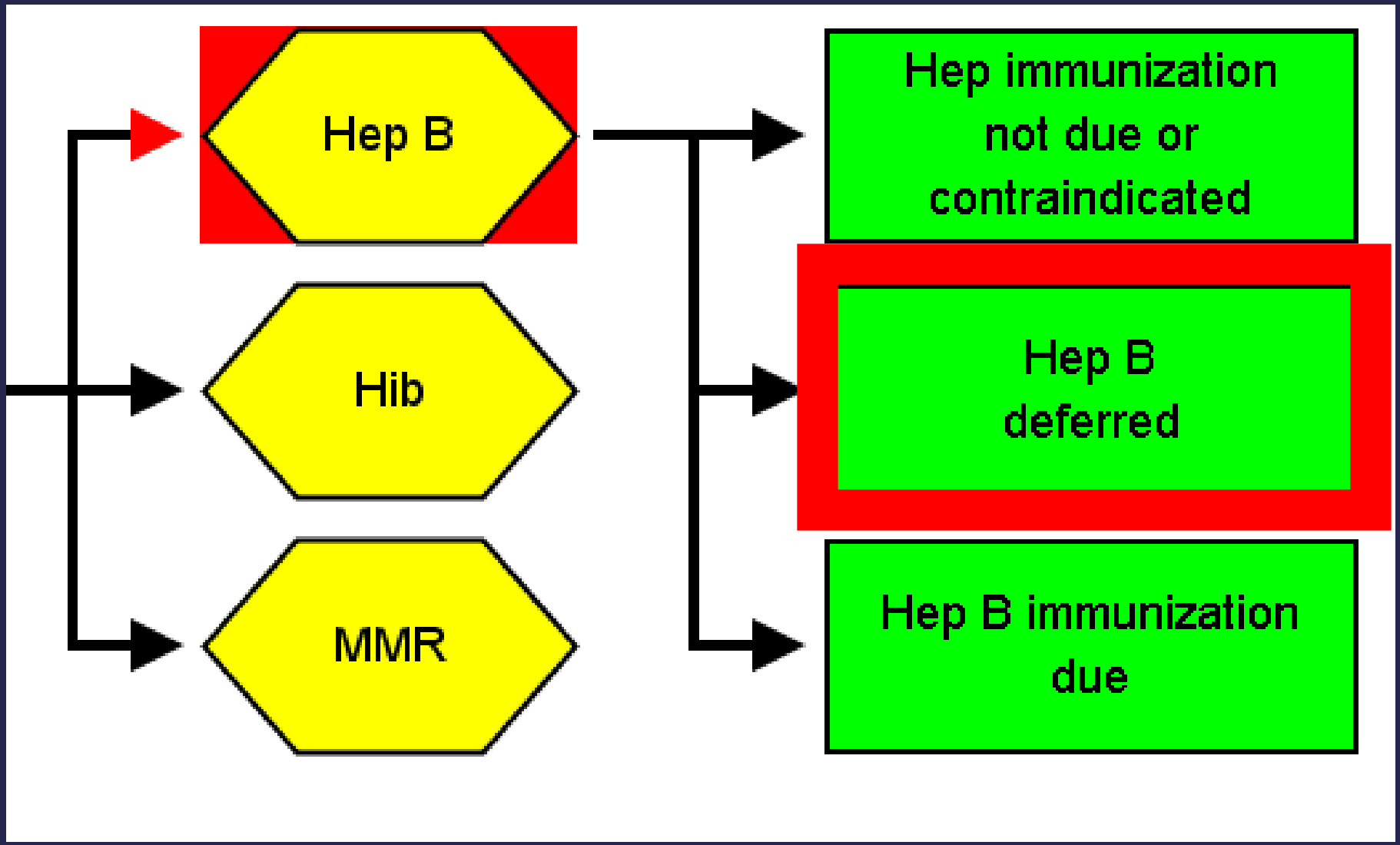

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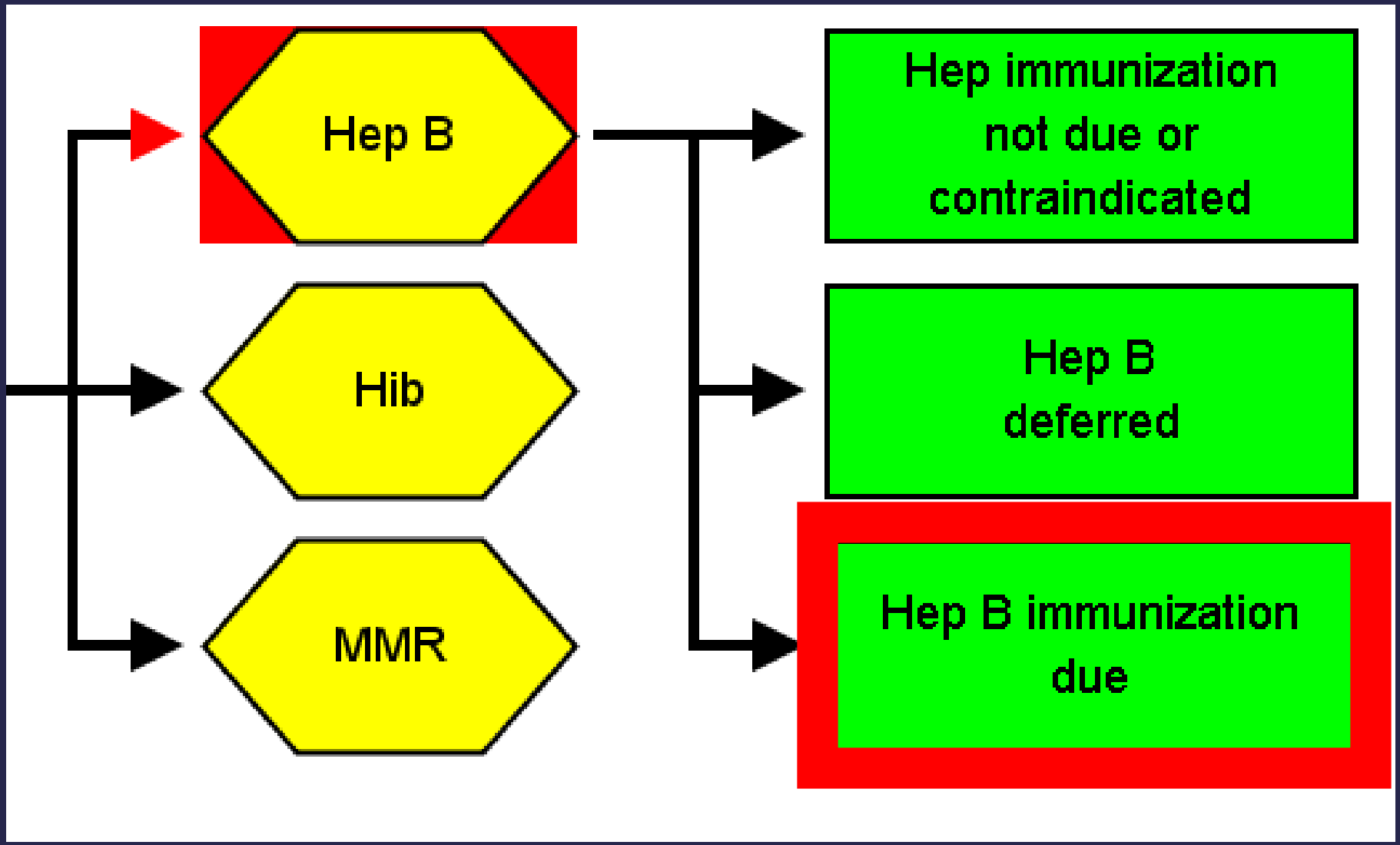
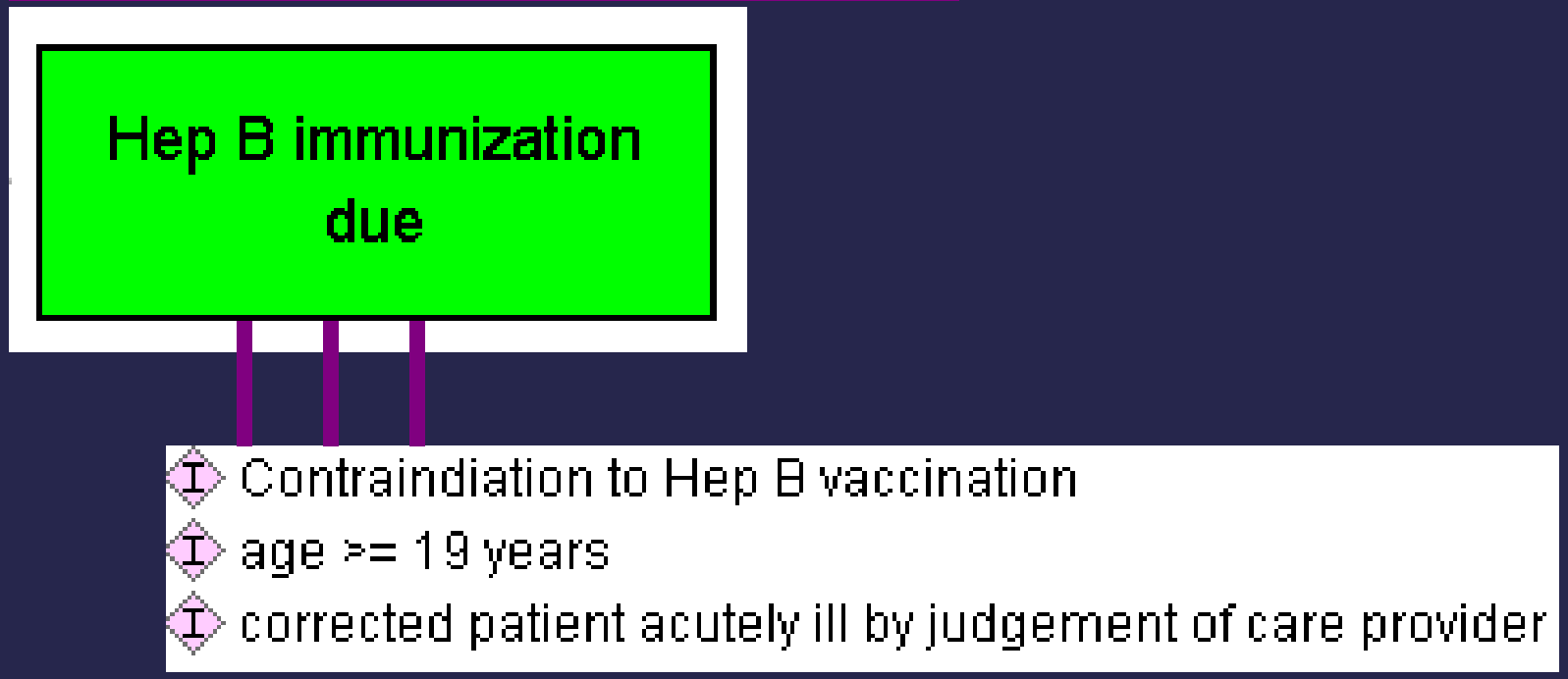


Rule Out: Any 1 of these



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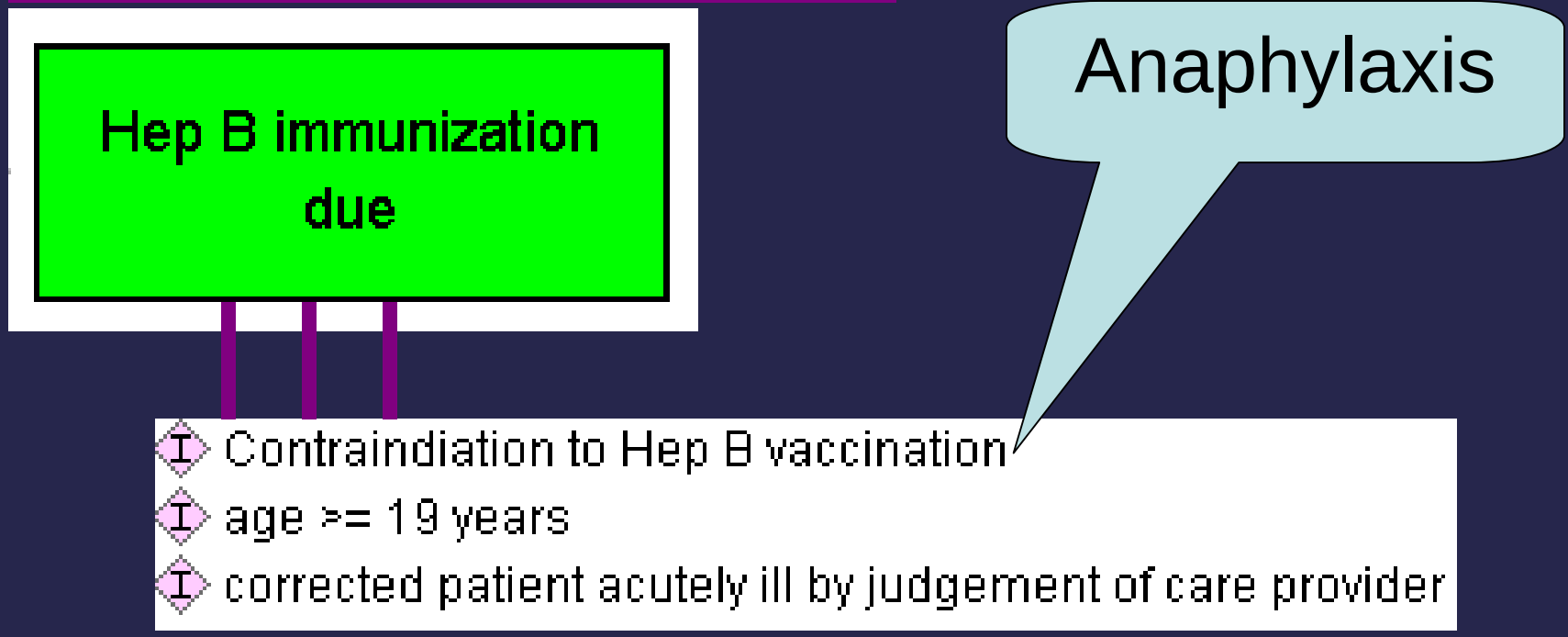

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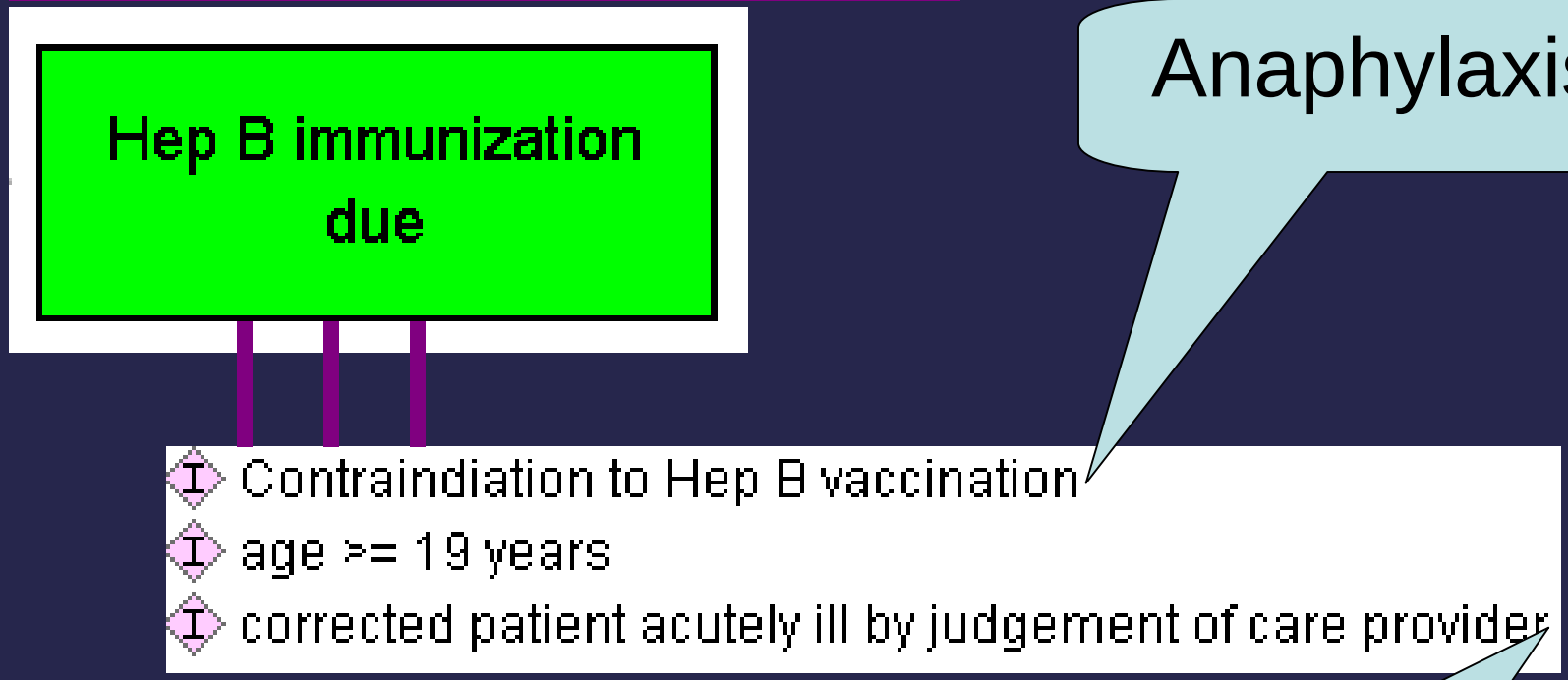


Anaphylaxis

Observation today of SNOMED-CT 39104002 = Illness

Rule In, ANY ONE OF:

Hep B immunization due

- no previous hep B vaccination and age >= 1 months
- 1 previous Hep B dose, 4 weeks after first dose
- 2 Hep B doses already, 8 weeks after last dose, 16 weeks after 1st dose
- Birth dose given with early delivery of 3rd dose
- 1 previous Hep B dose, age >= 1 months, mother Hep B+
- age<7days, previous hep B vaccination

Rule In, ANY ONE OF:

Hep B immunization due

- no previous hep B vaccination and age >= 1 months **3**
- 1 previous Hep B dose, 4 weeks after first dose **2**
- 2 Hep B doses already, 8 weeks after last dose, 16 weeks after 1st dose **3**
- Birth dose given with early delivery of 3rd dose **4**
- 1 previous Hep B dose, age >= 1 months, mother Hep B+ **3**
- age<7days, previous hep B vaccination **3**

Rule In, ANY ONE OF:

Hep B immunization due

All N-ary criteria

no previous hep B vaccination and age >= 1 months	3
1 previous Hep B dose, 4 weeks after first dose	2
2 Hep B doses already, 8 weeks after last dose, 16 weeks after 1st dose	3
Birth dose given with early delivery of 3rd dose	4
1 previous Hep B dose, age >= 1 months, mother Hep B+	3
age<7days, previous hep B vaccination	3

Rule In, ANY ONE OF:

Hep B immunization due

All of these must be true

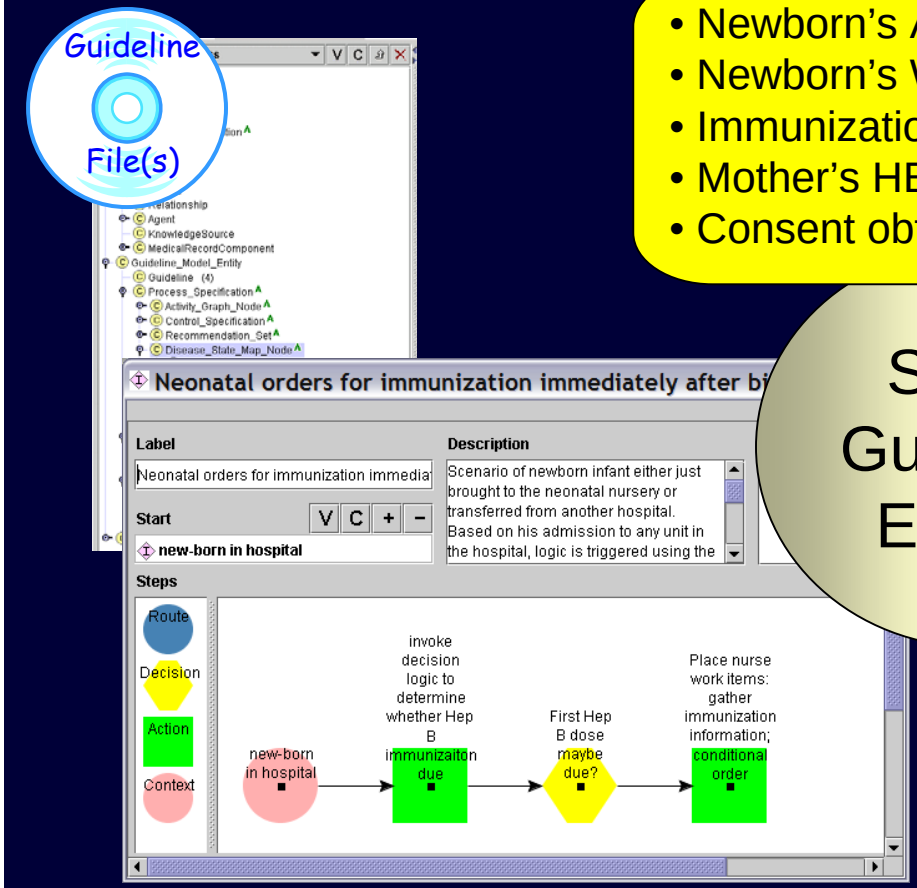
- age < 7 days
- # of hep B doses = 0
- Mother Hep B+

(and)

All N-ary criteria

no previous hep B vaccination and age >=	
1 previous Hep B dose, 4 weeks after first do	2
2 Hep B doses already, 8 weeks after last d 16 weeks after 1st dose	3
Birth dose given with early delivery of 3rd d	4
1 previous Hep B dose, age >= 1 months, mother Hep B+	3
age<7days, previous hep B vaccination	3

SAGE Guideline Execution:
Neonatal Orders for Immunization



- Newborn's Age
- Newborn's Weight
- Immunization Hx
- Mother's HBsAG
- Consent obtained?

Local
Clinical Information System

Queries

EMR Data

SAGE
Guideline
Engine

Patient
Record

Events

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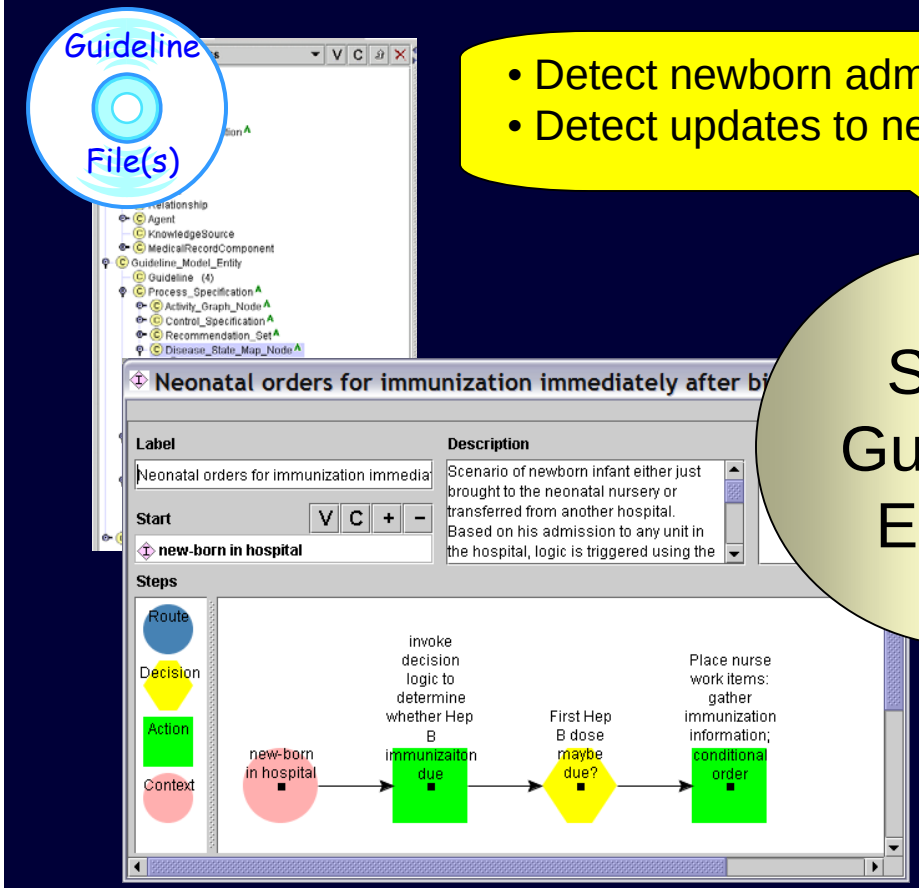
Actions

Order
Entry

Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.

SAGE Guideline Execution:
Neonatal Orders for Immunization



- Detect newborn admission
- Detect updates to newborn's EMR

Local Clinical Information System

SAGE Guideline Engine

Queries

MR Data

Events

Actions

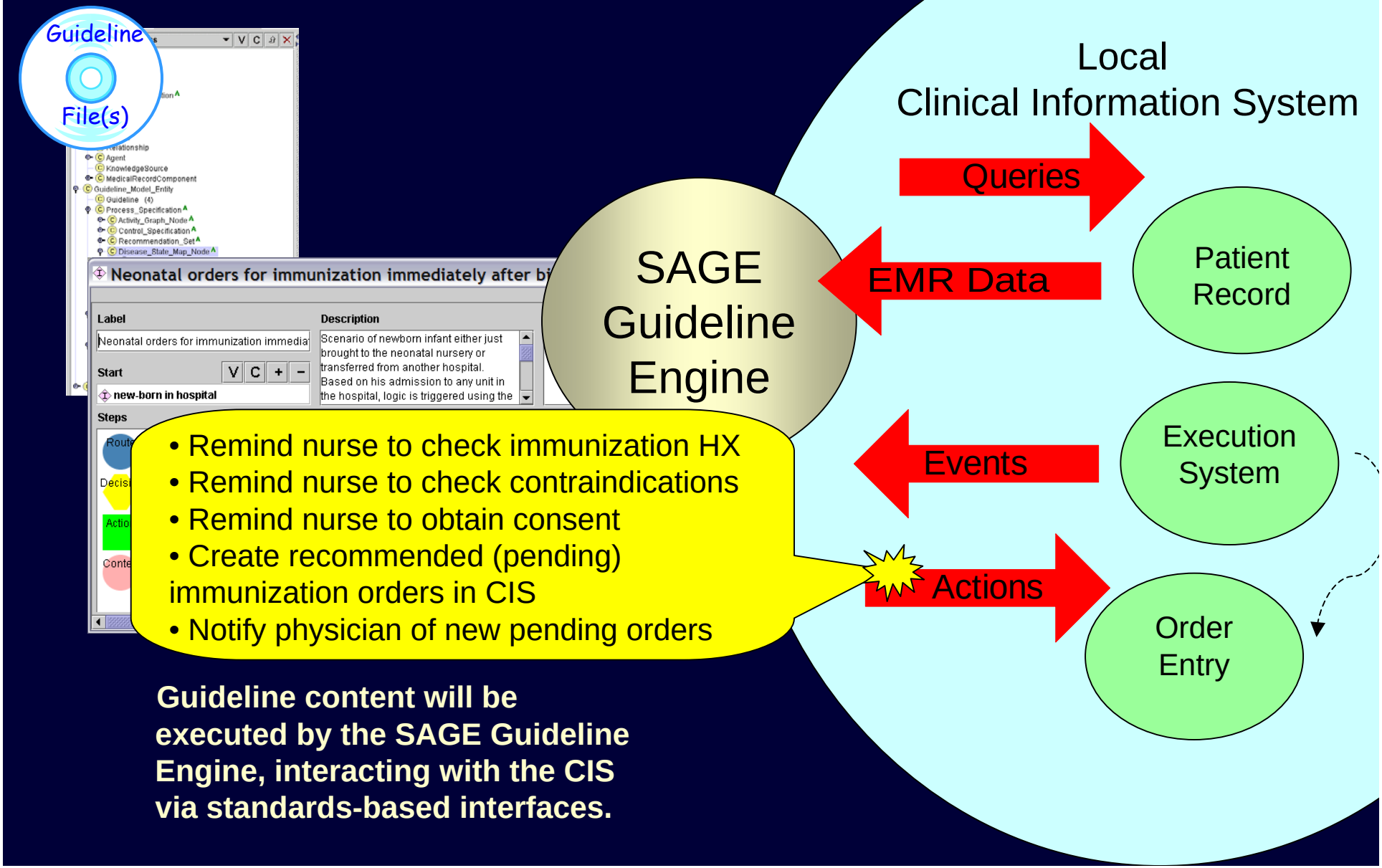
Patient Record

Execution System

Order Entry

Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.

SAGE Guideline Execution:
Neonatal Orders for Immunization



Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.

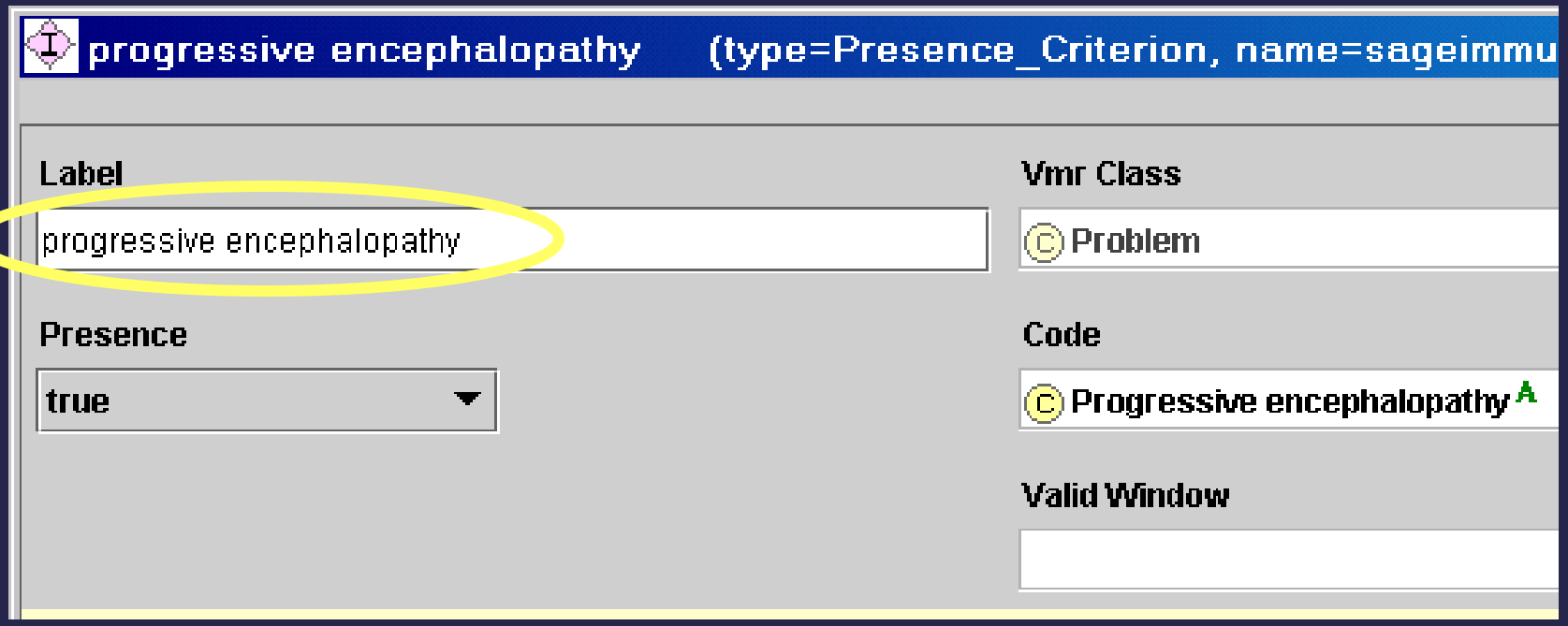
Neonate w/ HepB positive mother

Not So Simple

1. Triggering event: SAGE engine detects newborn admission.
2. "Automatic enrollment": SAGE enrolls new patient.
3. Context node: Obtain and check patient age.
4. Decision node: Compute vaccinations that are due.
    a. **Evaluate MMR and HepB.**
    b. Query child's record re: # of past immunizations.
    c. Mother's HBsAG status (CEM)
5. CEM-based query: Has consent been obtained?
6. CEM-based query: Obtain child's weight.
7. Concept Expression: e.g., "progressive encepthalopathy"
8. SAGE-initiated action: Non-active orders sent to CIS.
9. SAGE-initiated action: Inbox.

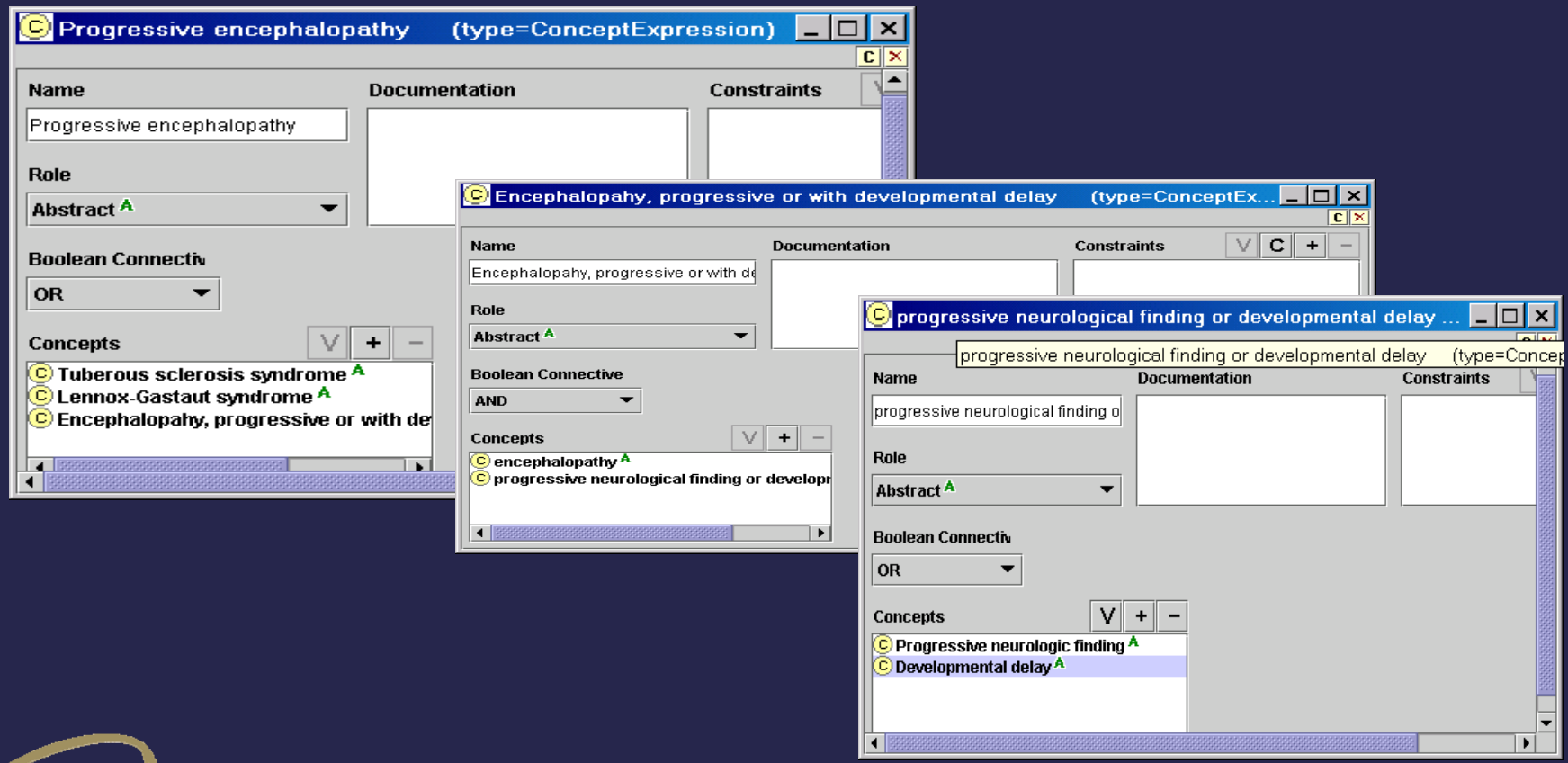
Concept Expressions

- DTaP should be deferred if following presence criterion evaluates to true

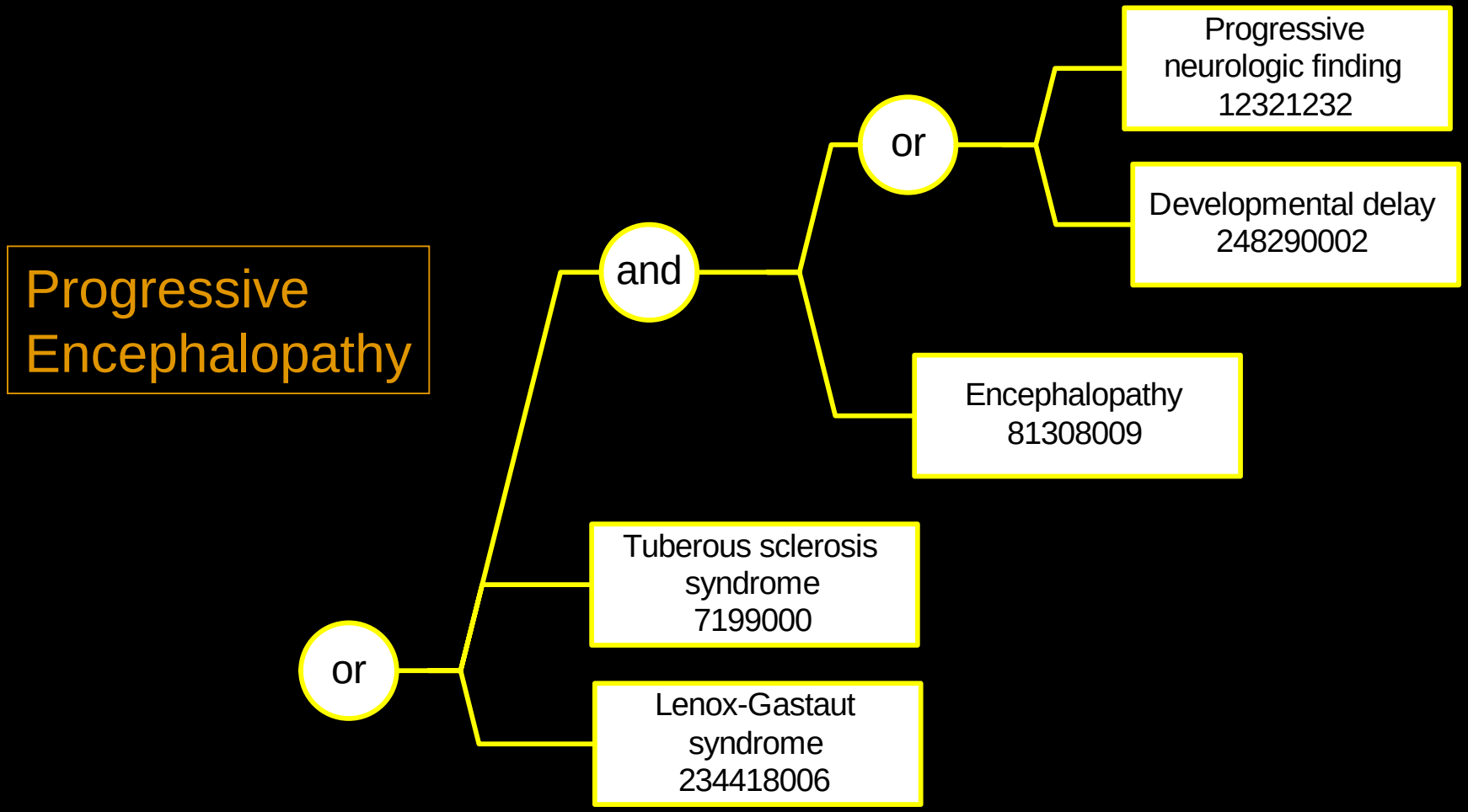


Concept Expressions

- Progressive Encephalopathy is encoded as

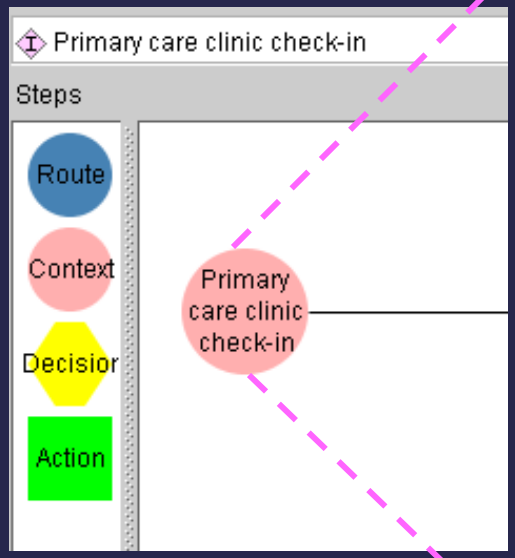


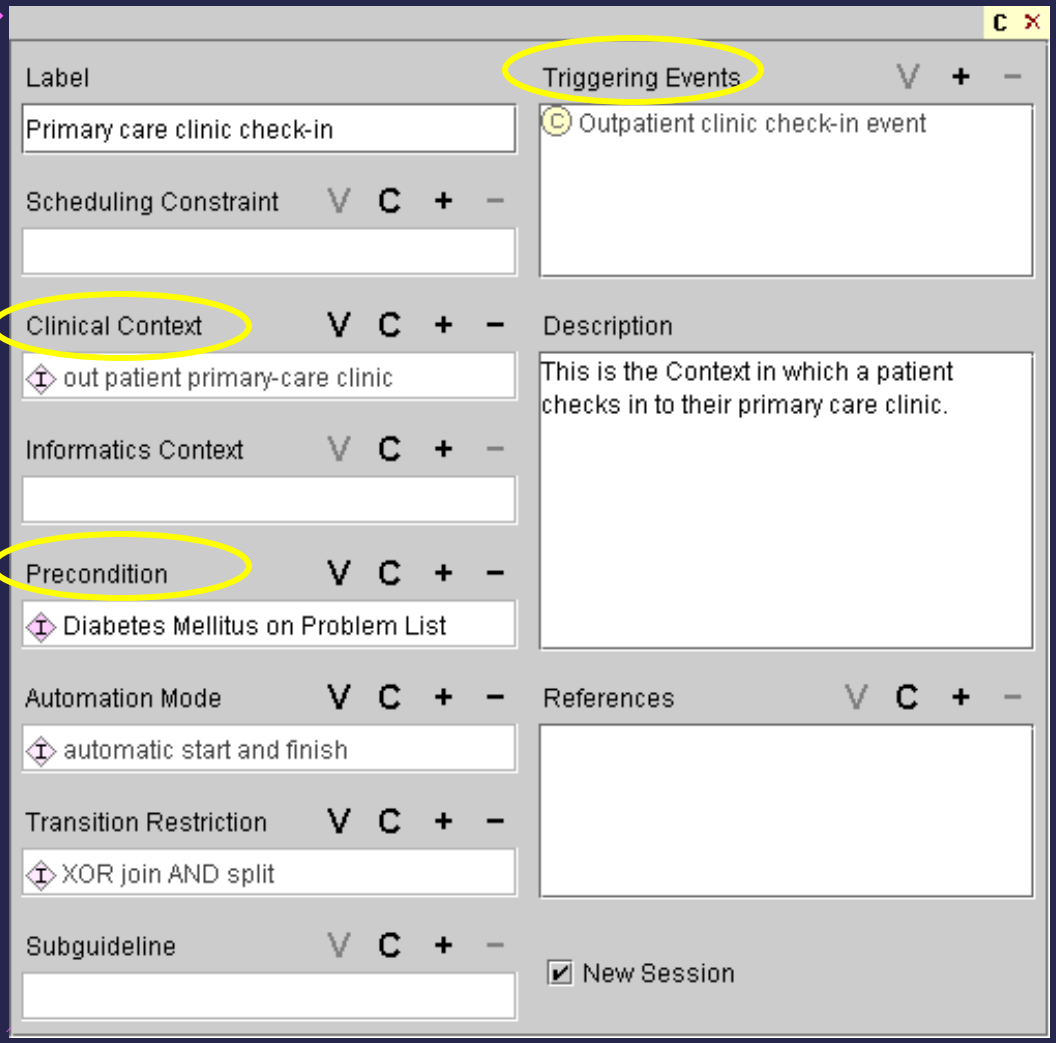
Boolean using SNOMED-CT codes



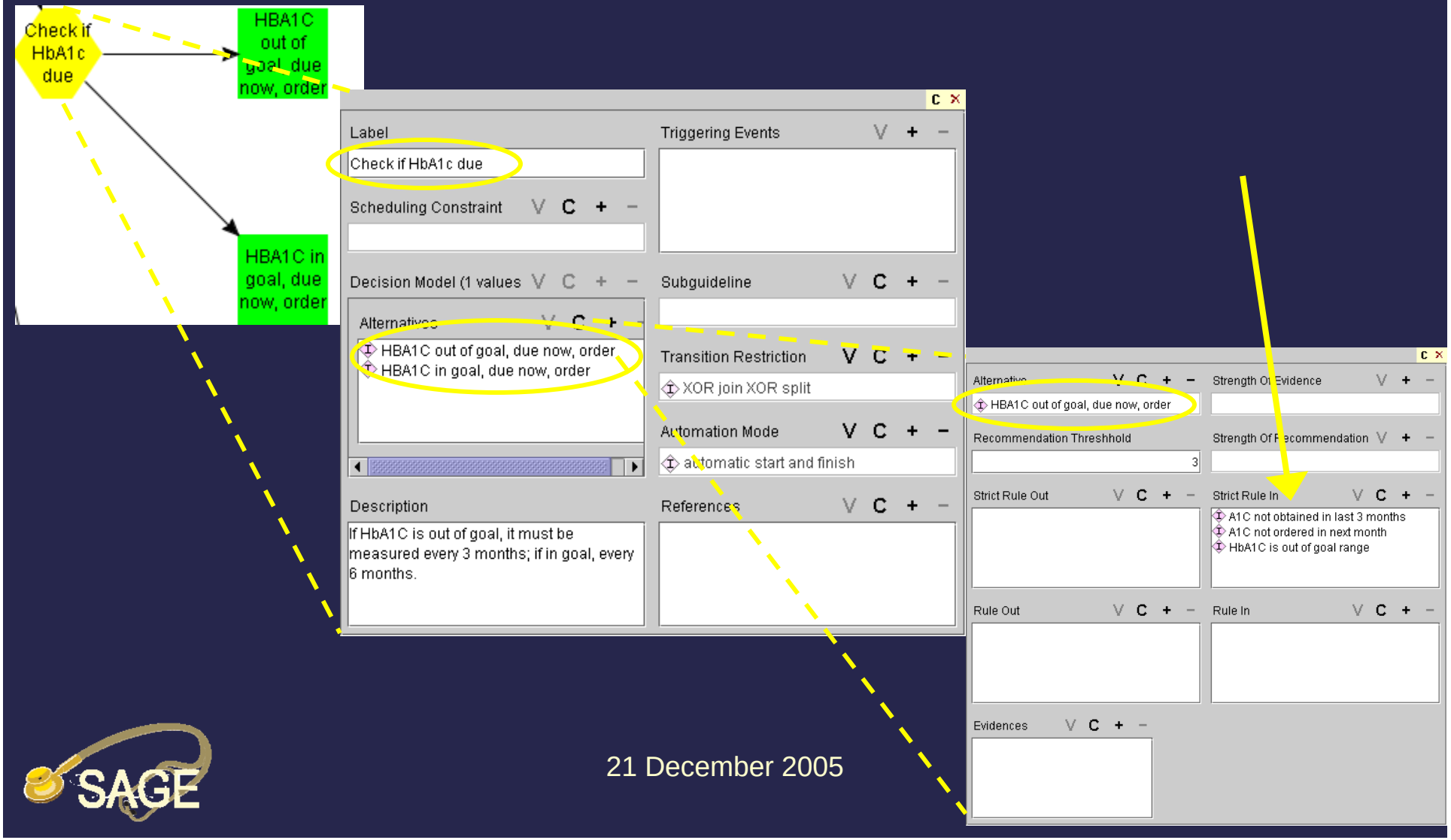
Guideline Execution:

SAGE listens for and detects context-specific events



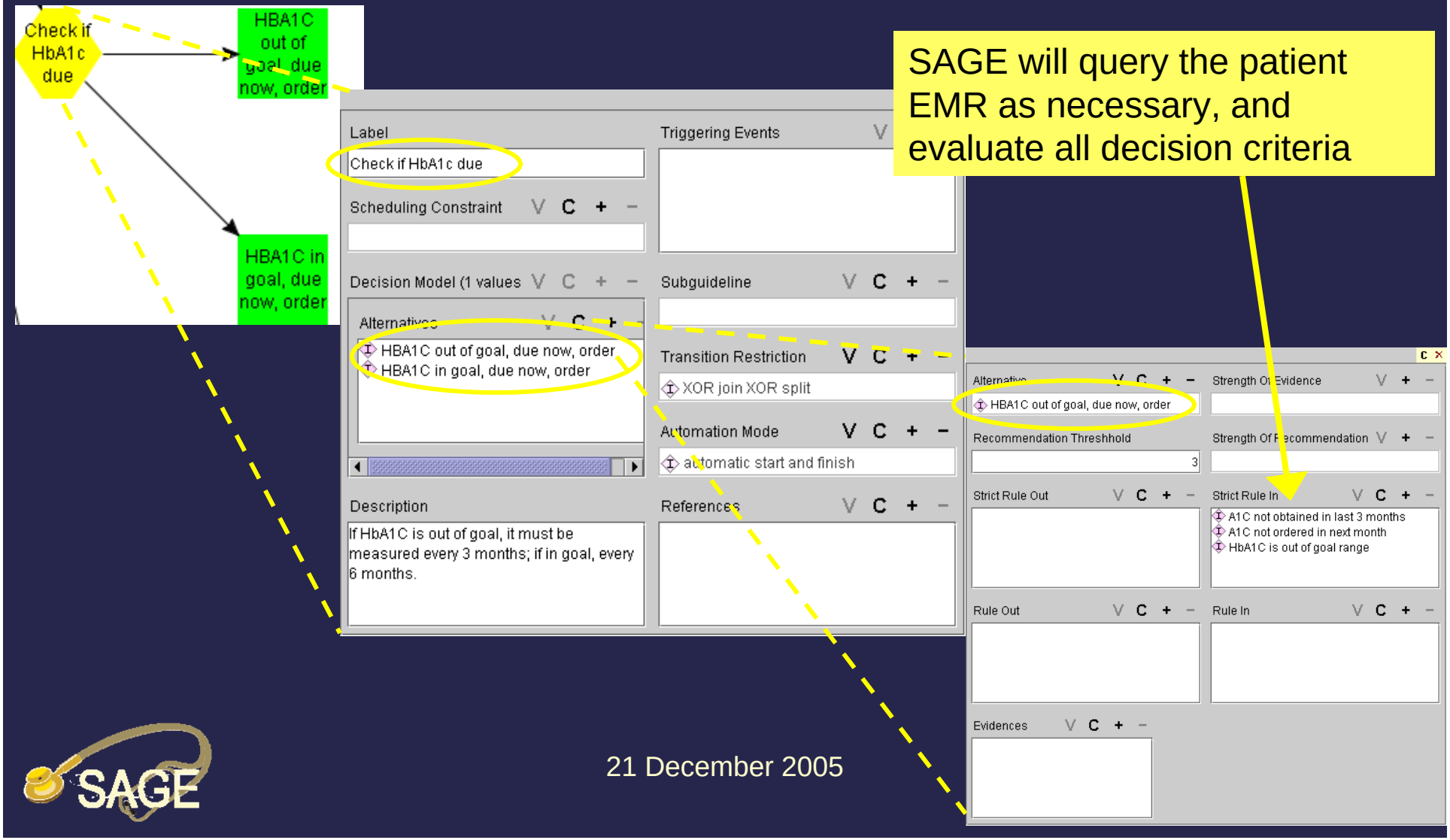


SAGE executes encoded decision logic

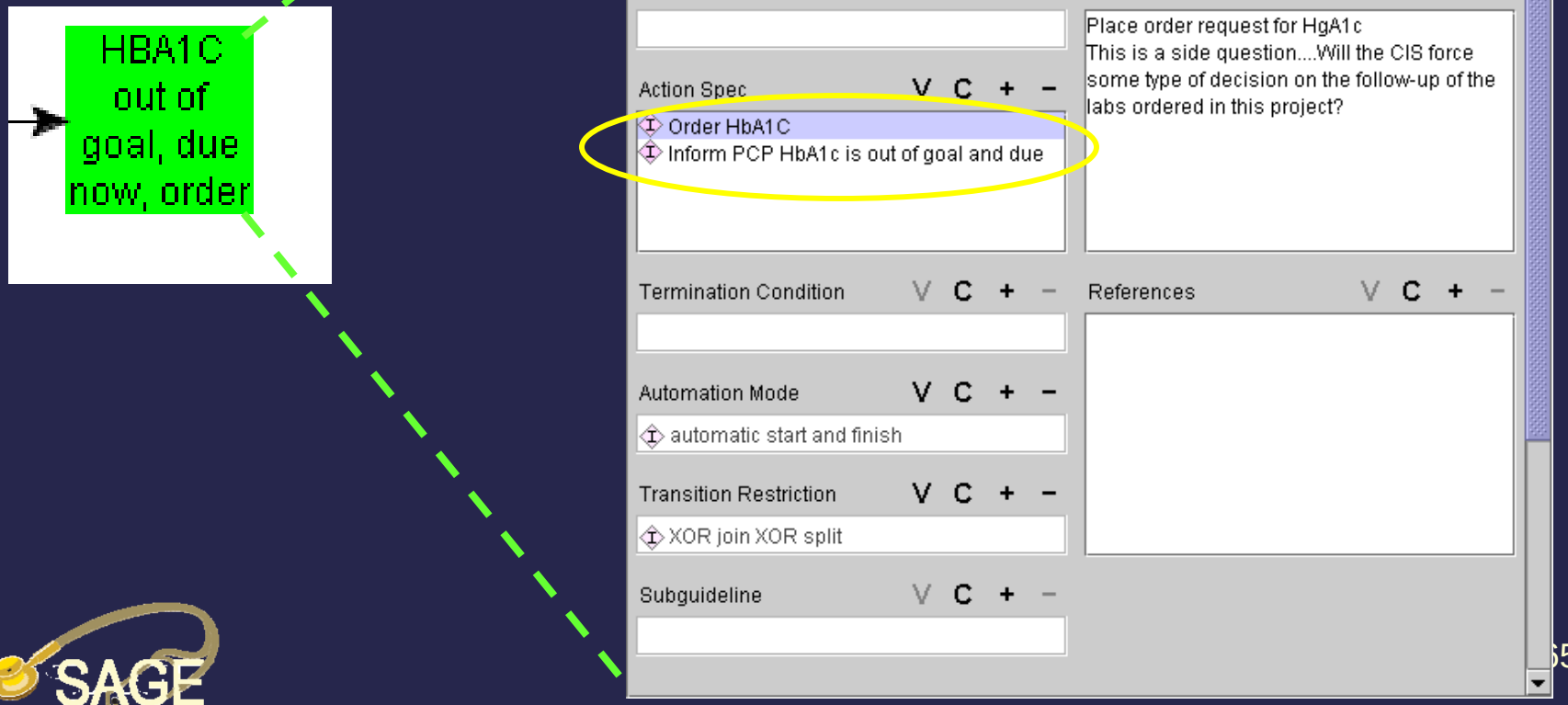


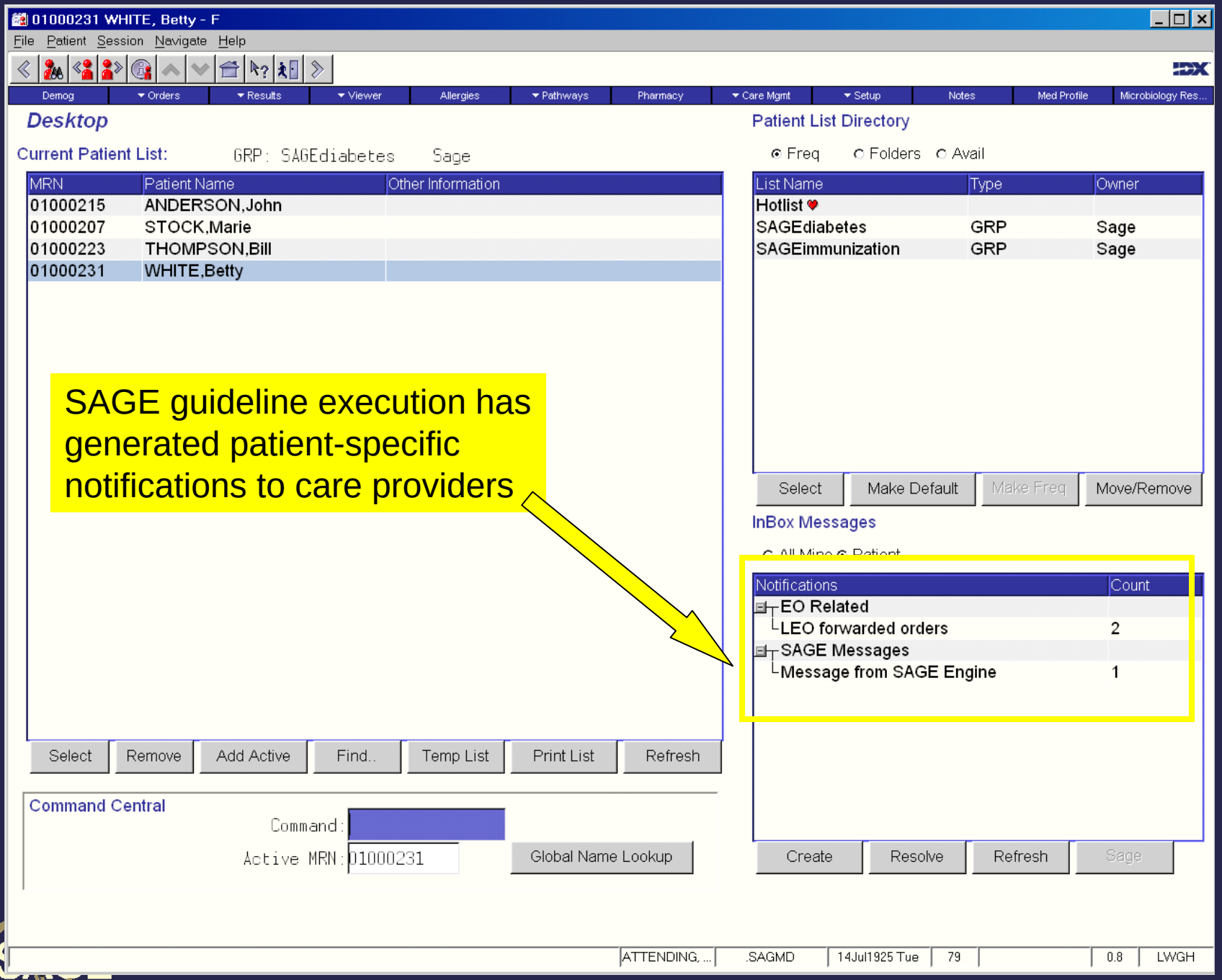
Guideline Execution:

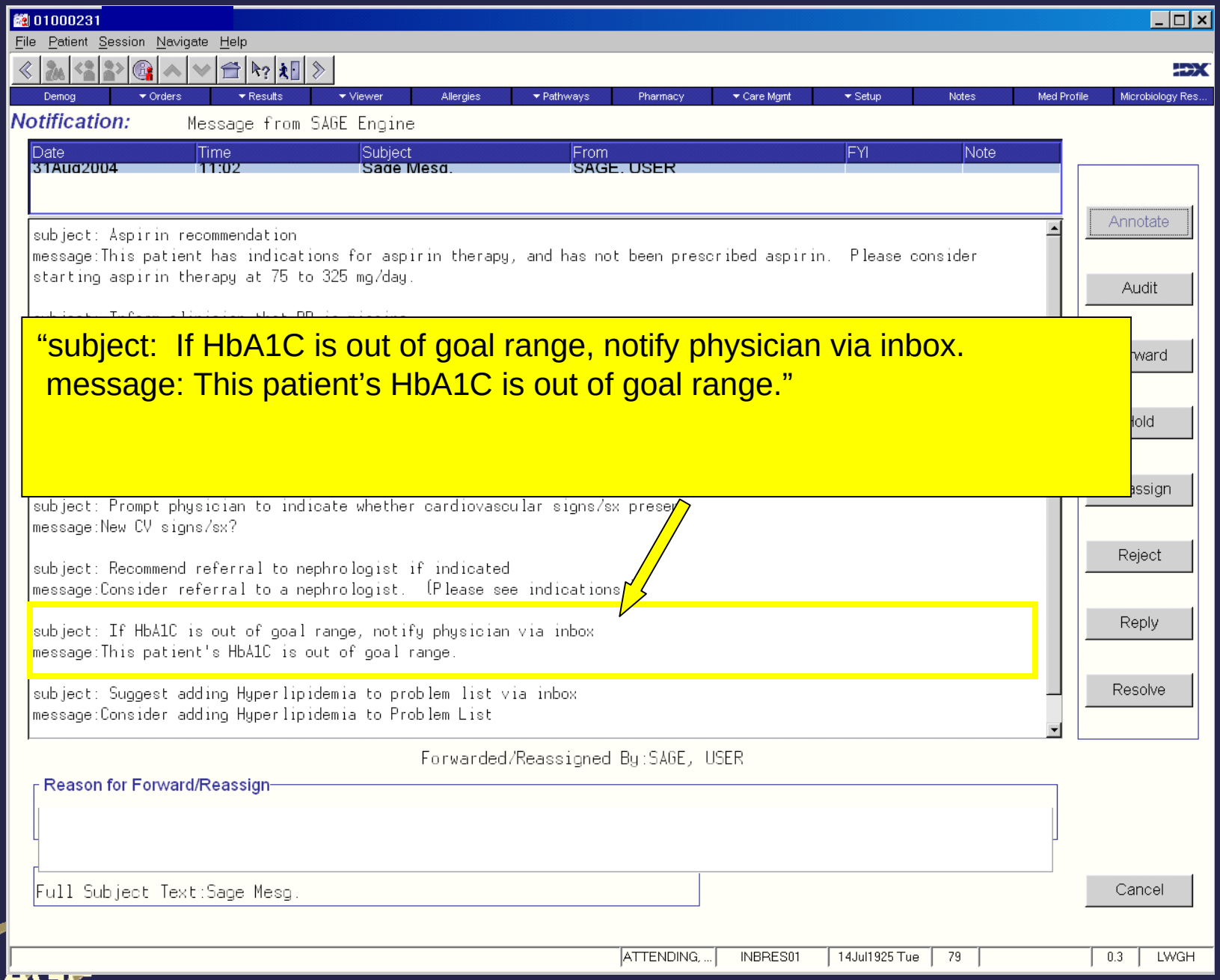
SAGE executes encoded decision logic

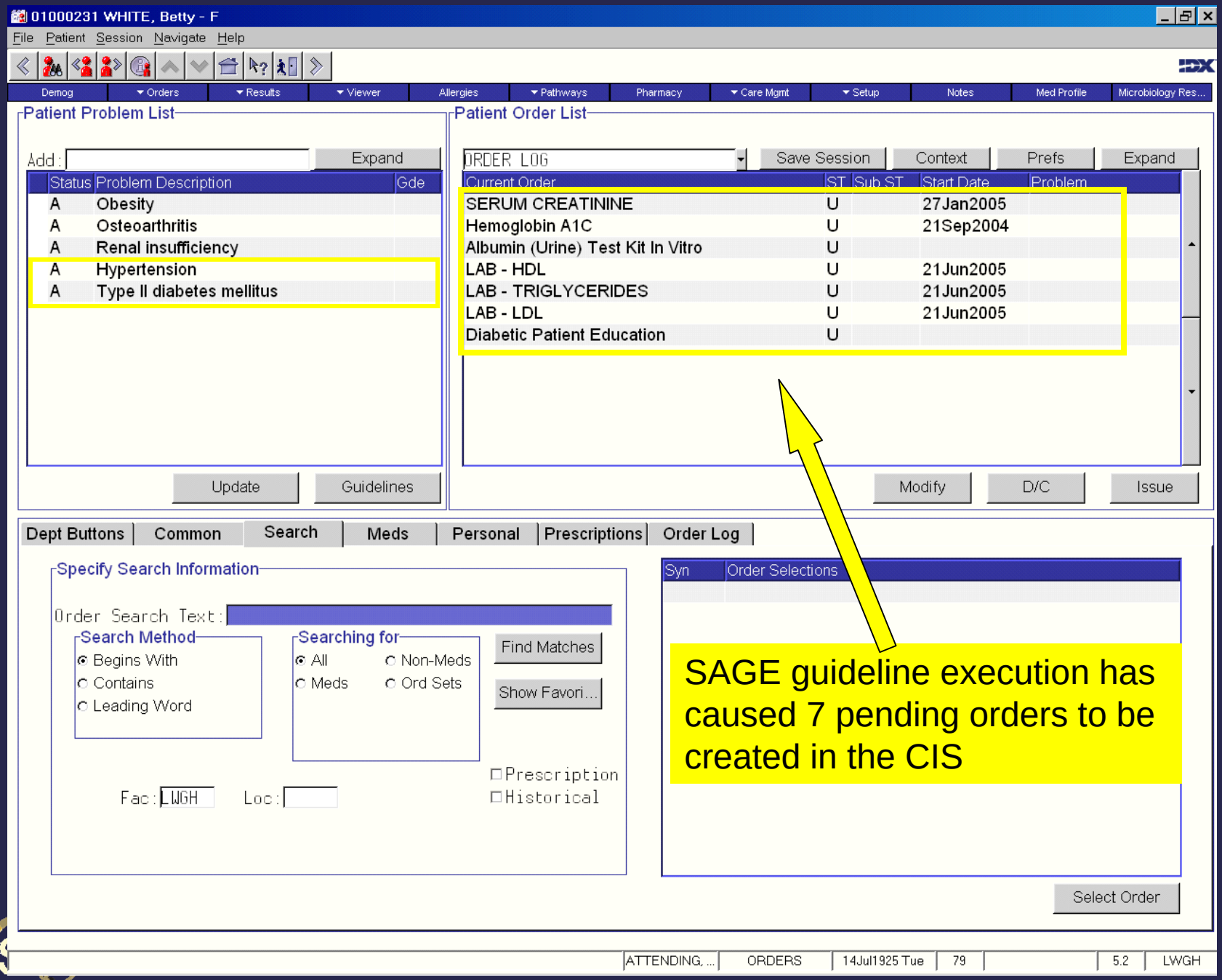


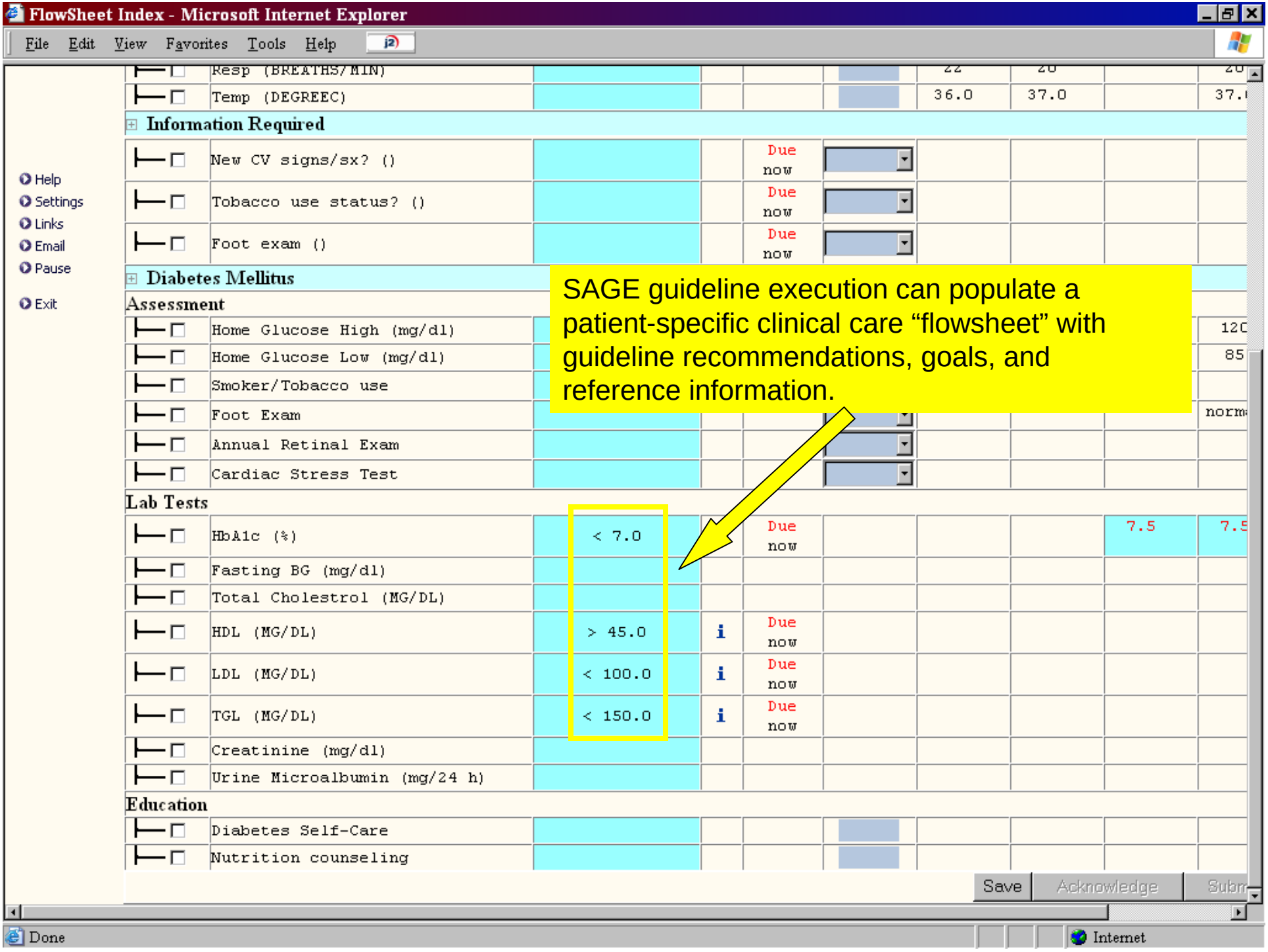
SAGE communicates actions to the CIS

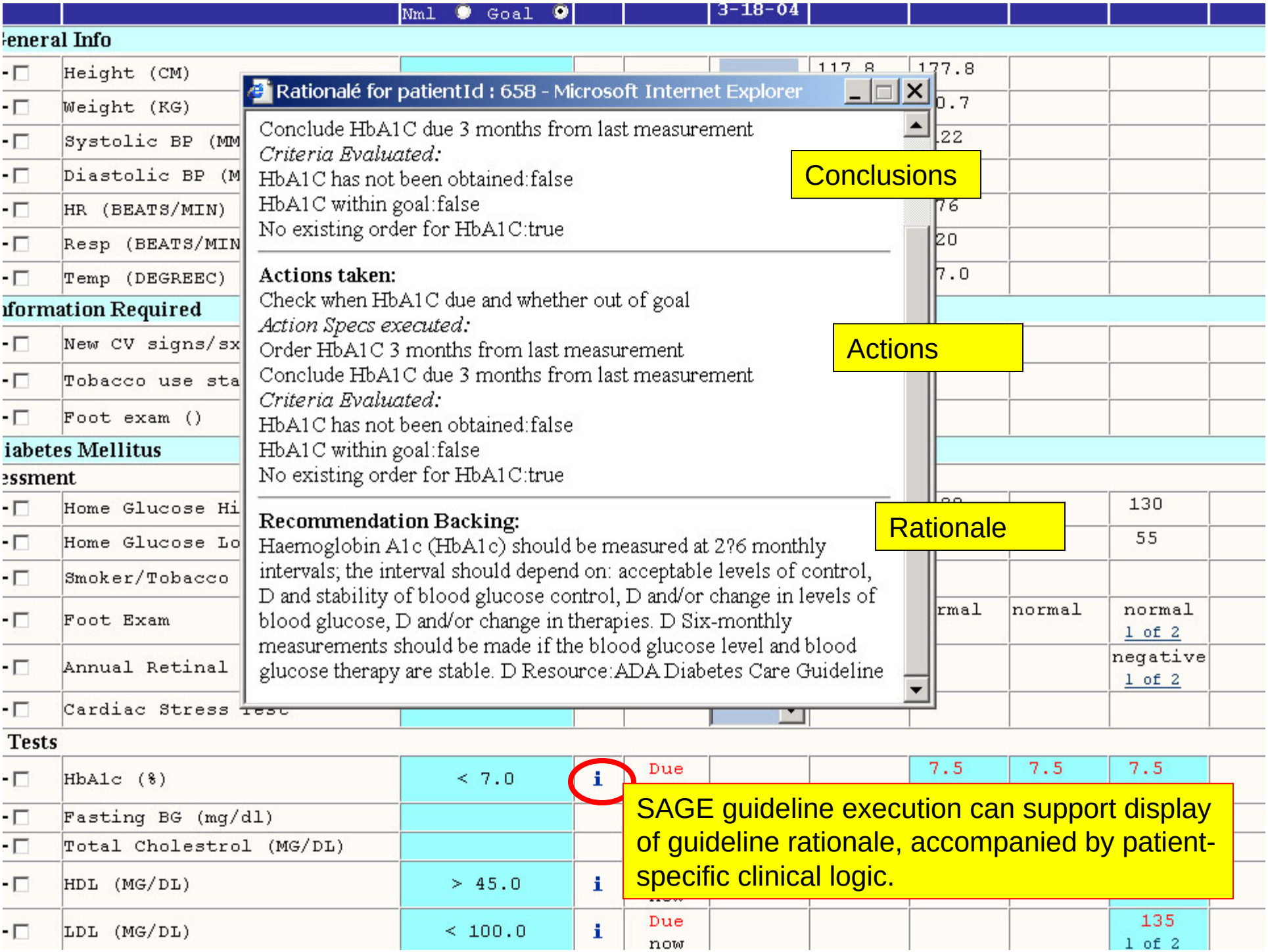



01000231 WHITE, Betty - F
File Patient Session Navigate Help
Demog Orders Results Viewer Allergies Pathways Pharmacy Care Mgmt Setup Notes Med Profile Microbiology Res...
Desktop
Current Patient List: GRP: SAGEdiabetes Sage
MRN Patient Name Other Information
01000215 ANDERSON,John
01000207 STOCK,Marie
01000223 THOMPSON,Bill
01000231 WHITE,Betty
SAGE guideline execution has generated patient-specific notifications to care providers
Select Remove Add Active Find.. Temp List Print List Refresh
Command Central
Command:
Active MRN: 01000231
Global Name Lookup
Patient List Directory
Freq Folders Avail
List Name Type Owner
Hotlist
SAGEdiabetes GRP Sage
SAGEimmunization GRP Sage
Select Make Default Make Freq Move/Remove
InBox Messages
Notifications Count
EO Related
LEO forwarded orders 2
SAGE Messages
Message from SAGE Engine 1
Create Resolve Refresh Sage
ATTENDING, ...SAGMD 14Jul1925 Tue 79 0.8 LWGH


01000231
File Patient Session Navigate Help
Demog Orders Results Viewer Allergies Pathways Pharmacy Care Mgmt Setup Notes Med Profile Microbiology Res...
Notification: Message from SAGE Engine
Date Time Subject From FYI Note
31Aug2004 11:02 Sage Mesg. SAGE, USER
subject: Aspirin recommendation
message:This patient has indications for aspirin therapy, and has not been prescribed aspirin. Please consider starting aspirin therapy at 75 to 325 mg/day.
"subject: If HbA1C is out of goal range, notify physician via inbox.
message: This patient's HbA1C is out of goal range."
subject: Prompt physician to indicate whether cardiovascular signs/sx prese
message:New CV signs/sx?
subject: Recommend referral to nephrologist if indicated
message:Consider referral to a nephrologist. (Please see indications
subject: If HbA1C is out of goal range, notify physician via inbox
message:This patient's HbA1C is out of goal range.
subject: Suggest adding Hyperlipidemia to problem list via inbox
message:Consider adding Hyperlipidemia to Problem List
Annotate
Audit
ward
old
ssign
Reject
Reply
Resolve
Forwarded/Reassigned By:SAGE, USER
Reason for Forward/Reassign
Full Subject Text:Sage Mesg.
Cancel
ATTENDING, ... INBRES01 14Jul1925 Tue 79 0.3 LWGH


01000231 WHITE, Betty - F
File Patient Session Navigate Help
Demog Orders Results Viewer Allergies Pathways Pharmacy Care Mgmt Setup Notes Med Profile Microbiology Res...
Patient Problem List
Add:
Expand
Status Problem Description Gde
A Obesity
A Osteoarthritis
A Renal insufficiency
A Hypertension
A Type II diabetes mellitus
Update
Guidelines
Patient Order List
ORDER LOG
Save Session
Context
Prefs
Expand
Current Order ST Sub ST Start Date Problem
SERUM CREATININE U 27Jan2005
Hemoglobin A1C U 21Sep2004
Albumin (Urine) Test Kit In Vitro U
LAB - HDL U 21Jun2005
LAB - TRIGLYCERIDES U 21Jun2005
LAB - LDL U 21Jun2005
Diabetic Patient Education U
Modify
D/C
Issue
Dept Buttons Common Search Meds Personal Prescriptions Order Log
Specify Search Information
Order Search Text:
Search Method
Begins With
Contains
Leading Word
Searching for
All
Non-Meds
Meds
Ord Sets
Find Matches
Show Favori...
Prescription
Historical
Fac: LWGH
Loc:
Syn Order Selections
Select Order
SAGE guideline execution has caused 7 pending orders to be created in the CIS
ATTENDING, ... ORDERS 14Jul1925 Tue 79 5.2 LWGH


FlowSheet Index - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Resp (BREATHS/MIN) 22 20
Temp (DEGREEC) 36.0 37.0 37.
Information Required
New CV signs/sx? ()
Tobacco use status? ()
Foot exam ()
Due now
Help
Settings
Links
Email
Pause
Exit
Diabetes Mellitus
Assessment
Home Glucose High (mg/dl) 120
Home Glucose Low (mg/dl) 85
Smoker/Tobacco use
Foot Exam norm
Annual Retinal Exam
Cardiac Stress Test
Lab Tests
HbA1c (%) < 7.0 7.5 7.5
Fasting BG (mg/dl)
Total Cholestrol (MG/DL)
HDL (MG/DL) > 45.0
LDL (MG/DL) < 100.0
TGL (MG/DL) < 150.0
Creatinine (mg/dl)
Urine Microalbumin (mg/24 h)
Education
Diabetes Self-Care
Nutrition counseling
SAGE guideline execution can populate a patient-specific clinical care "flowsheet" with guideline recommendations, goals, and reference information.
Save
Acknowledge
Done
Internet


Nml
Goal
3-18-04
eneral Info
Height (CM)
Weight (KG)
Systolic BP (MM
Diastolic BP (M
HR (BEATS/MIN)
Resp (BEATS/MIN
Temp (DEGREEC)
177.8
0.7
22
76
20
7.0
formation Required
New CV signs/sx
Tobacco use sta
Foot exam ()
iabetes Mellitus
essment
Home Glucose Hi
Home Glucose Lo
Smoker/Tobacco
Foot Exam
Annual Retinal
Cardiac Stress Test
130
55
rmal
normal
normal
1 of 2
negative
1 of 2
Rationalé for patientId : 658 - Microsoft Internet Explorer
Conclude HbA1C due 3 months from last measurement
Criteria Evaluated:
HbA1C has not been obtained:false
HbA1C within goal:false
No existing order for HbA1C:true
Actions taken:
Check when HbA1C due and whether out of goal
Action Specs executed:
Order HbA1C 3 months from last measurement
Conclude HbA1C due 3 months from last measurement
Criteria Evaluated:
HbA1C has not been obtained:false
HbA1C within goal:false
No existing order for HbA1C:true
Recommendation Backing:
Haemoglobin A1c (HbA1c) should be measured at 2?6 monthly intervals; the interval should depend on: acceptable levels of control, D and stability of blood glucose control, D and/or change in levels of blood glucose, D and/or change in therapies. D Six-monthly measurements should be made if the blood glucose level and blood glucose therapy are stable. D Resource:ADA Diabetes Care Guideline
Conclusions
Actions
Rationale
Tests
HbA1c (%)
< 7.0
Due
7.5
7.5
7.5
Fasting BG (mg/dl)
Total Cholestrol (MG/DL)
HDL (MG/DL)
> 45.0
LDL (MG/DL)
< 100.0
Due now
135
1 of 2
SAGE guideline execution can support display of guideline rationale, accompanied by patient-specific clinical logic.

The SAGE Project
Standards-Based Sharable Active Guideline Environment

Accomplishments

We have:

- Shown that clinical guidelines can be encoded in a standards-based, sharable, computable format.
- Demonstrated the capability to represent complex guideline content and logic for both acute and chronic care domains.
- Used standard information models and terminologies to support interoperable transfer of medical knowledge.
- Addressed interoperability goals via:
  - A standards-based guideline model
  - A VMR-based interface to CIS
  - Standard web services to access EMR data
  - Standards based access to terminology services

The SAGE Project
Standards-Based Sharable Active Guideline Environment

Partial 2006 Plan

- Interoperability
  - Demonstrate interoperable transfer of medical knowledge
  - Tools to support deployment (mapping, binding, …)
- Standards
  - Tune vmr to emerging standards
  - Order Set Standard at HL7
- Demonstrations
  - Complete all three exemplars
  - ONCHIT and NIST
  - HIMSS
  - Surveillance study (Diabetes and Immunization)
- Final documentation
  - Reference CIS
  - Visible KB
  - Several publications

Azyxxi Collaboration

- Demonstrate interoperability: SAGE Engine runs w/ Azyxxi
- Audience: NIST, ONCHIT?, others?
- Time line: feasibility by 15 Feb, complete by 15 June
- Guideline: TBD
- Steps:
  - agreement, plan schedule and efforts
  - interface experiments
  - plan CIS side user experience
  - toy example
  - “real” possibly new guideline
  - plan for, announce, and execute demonstration