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From the Bench to Bedside Clinical Decision Support:

The Role of Semantic Technologies in a Knowledge Management Infrastructure for Translational Medicine

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Current State of Translational Medicine

- 17 year innovation adoption curve from discovery into accepted standards of practice
- Even if a standard is accepted, patients have a 50:50 chance of receiving appropriate care, a 5-10% probability of incurring a preventable, anticipatable adverse event
- The market is balking at healthcare inflation, new diagnostics and therapeutics will find increasing resistance for reimbursement
- Most EHRs are under-nourished with knowledge, knowledge is embedded in multiple disconnected legacy pools and difficult to maintain, EHR knowledge editors are primitive and disconnected from semantics
- Volume/velocity of knowledge processing exponentially growing, today we run at most 1000 rules at run time to manage an encounter, tomorrow, we'll need to answer 1000,000s of questions for every decision

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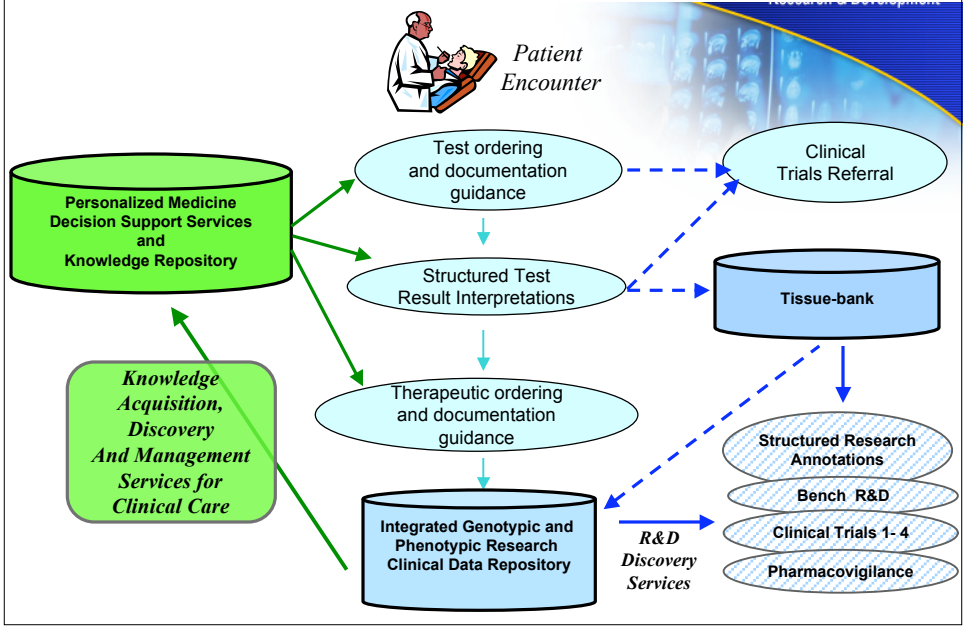
The Cytochrome P450 test…
new data to drive drug choice and dose
When do you order this test?
How do you use the test result?

WSJ.com THE WALL STREET JOURNAL. ONLINE

Leading the News: Roche Test Promises to Tailor Drugs to Patients --- Precise Genetic Approach Could Mean Major Changes In Development, Treatment

June 25, 2003
Roche Holding AG is launching the first gene test able to predict how a person will react to a large range of commonly prescribed medicines, one of the biggest forays yet into tailoring drugs to a patient's genetic makeup.
The test is part of an emerging approach to treatment that health experts expect could lead to big changes in the way drugs are developed, marketed and prescribed. For all of the advances in medicine, doctors today determine the best medicine and dose for an ailing patient largely by trial and error. The fast-growing field of "personalized" medicine hopes to remove such risks and alter the pharmaceutical industry's more one-size-fits-all approach in making and selling drugs.

Closing the Loop on Decision Support and Discovery
Depends on Shared Semantics



Role of Semantic Technologies in Healthcare and Lifesciences

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- Data/Knowledge Integration and Visualization
  - Ontology based approaches
  - Integration across multiple data sources:
    - Genotypic/Phenotypic data from LIMS/HER
    - Knowledge Repositories for data interpretation
- Clinical Decision Support
  - Inference engines - SWRL
  - Description logics for "recognition" - OWL
  - Knowledge representation
  - Etc.
- Knowledge Acquisition, Maintenance and Evolution
  - Ontology-based Definitions Management
  - Versioning, life-cycle, propagation into "dependent" objects such as rules, templates orders/documentation, reporting systems
  - Knowledge Provenance
  - Reconciling knowledge representation among different stakeholders (care givers, payors, performance measurement, clinical trials, R&D)

EGFR
epidermal growth factor receptor gene

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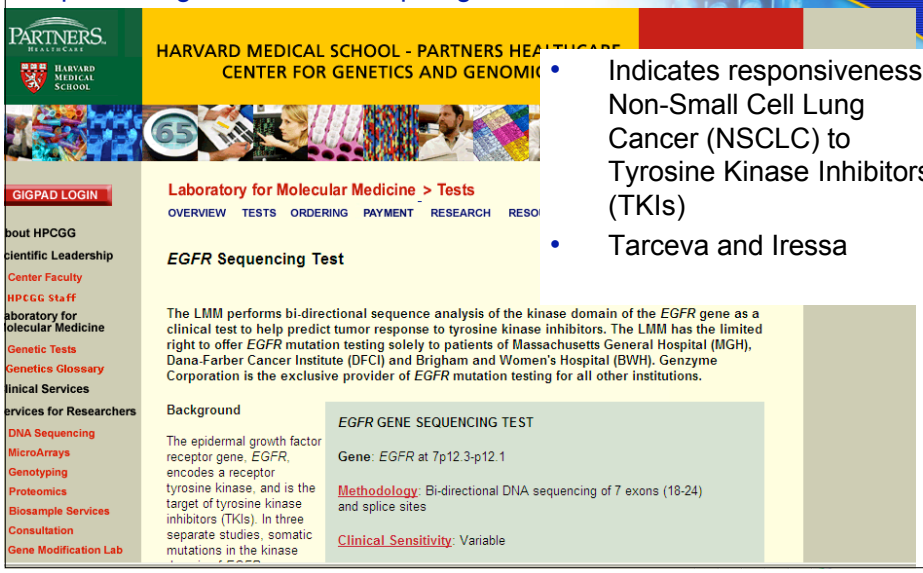

- Indicates responsiveness of Non-Small Cell Lung Cancer (NSCLC) to Tyrosine Kinase Inhibitors (TKIs)
- Tarceva and Iressa

Clinical processes for EGFR Testing

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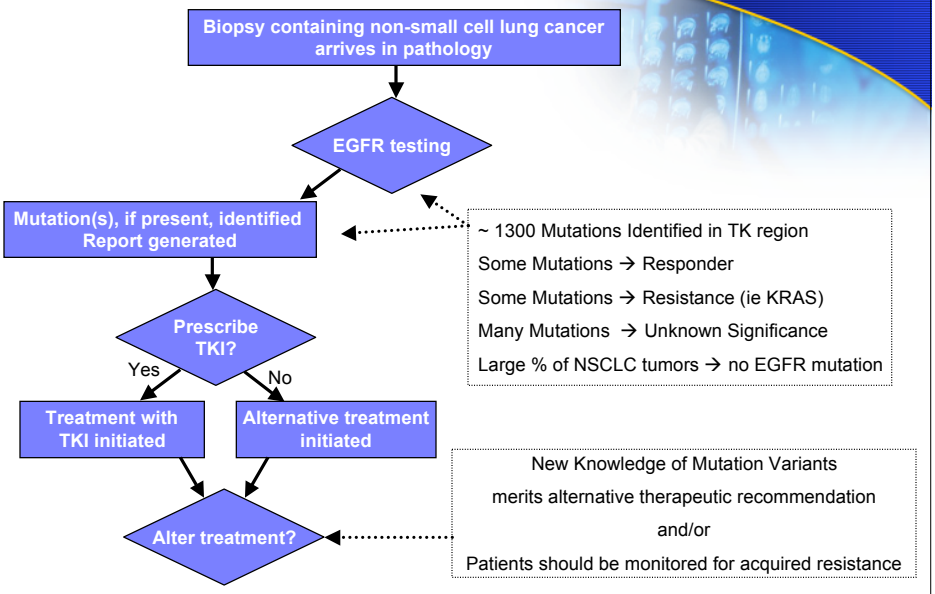

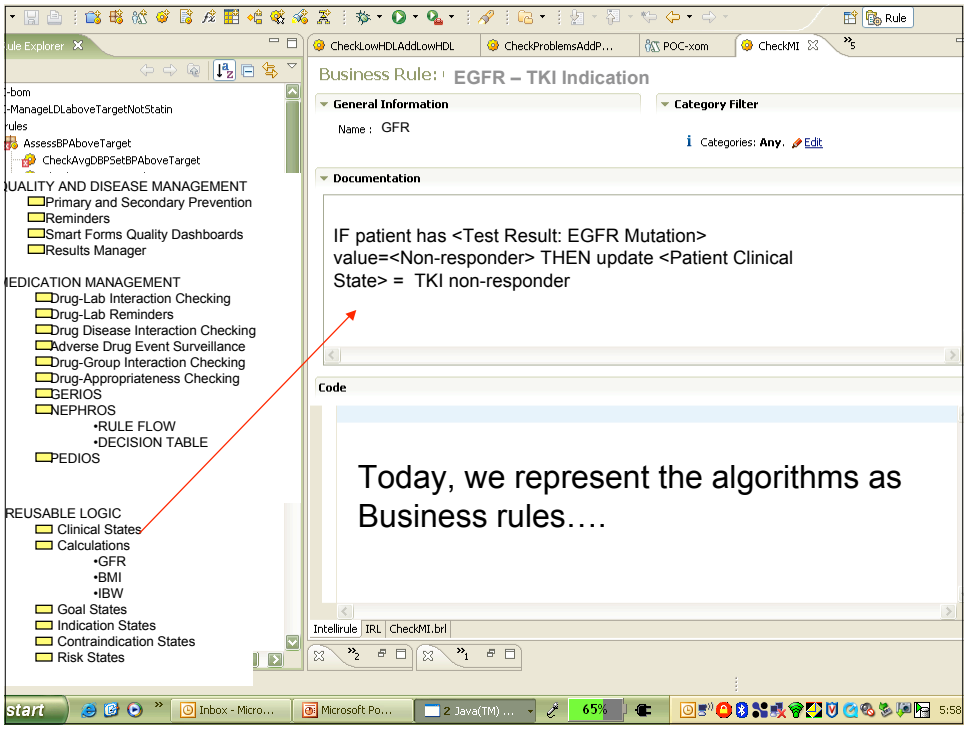

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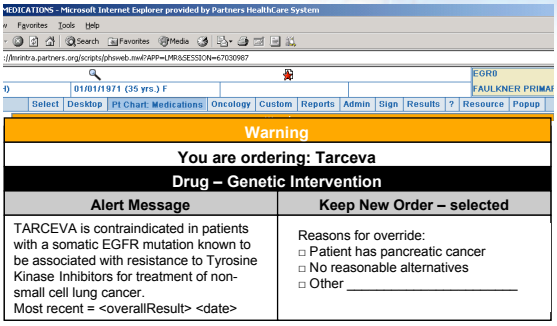
TKI Inhibitors – Knowledge-change Event Management

- Ongoing research means interpretation of EGFR test result will have continuously changing clinical significance
- Must model which changes warrant notification to change clinical management (new kind of classification rule)
- Must propagate these knowledge base changes into Rules, Documentation Templates and Quality and Safety Reporting Systems



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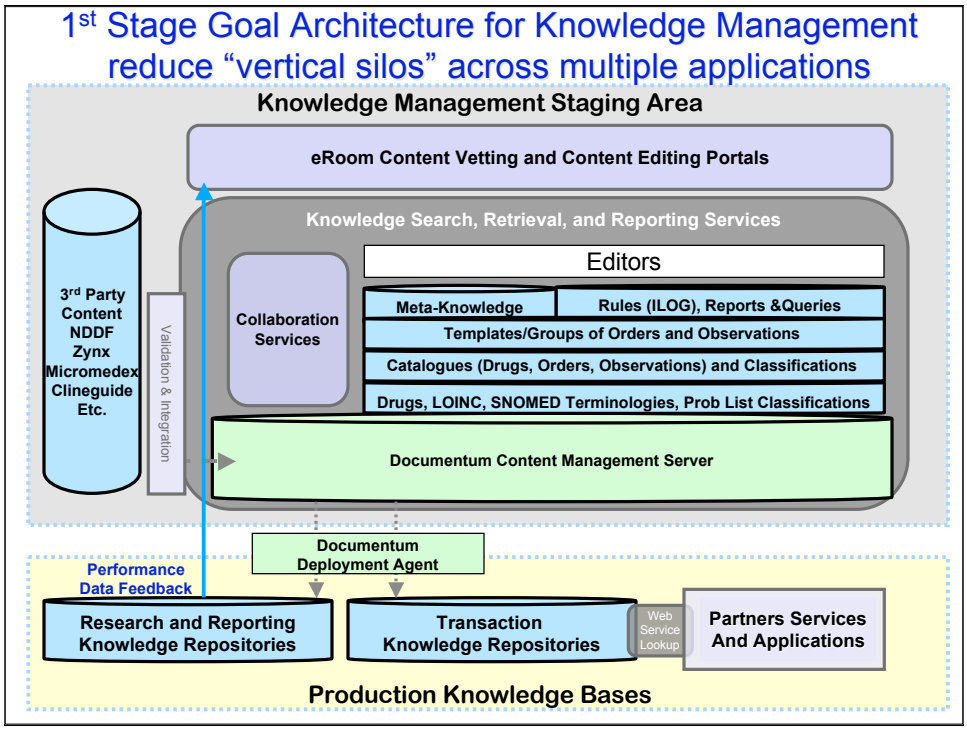
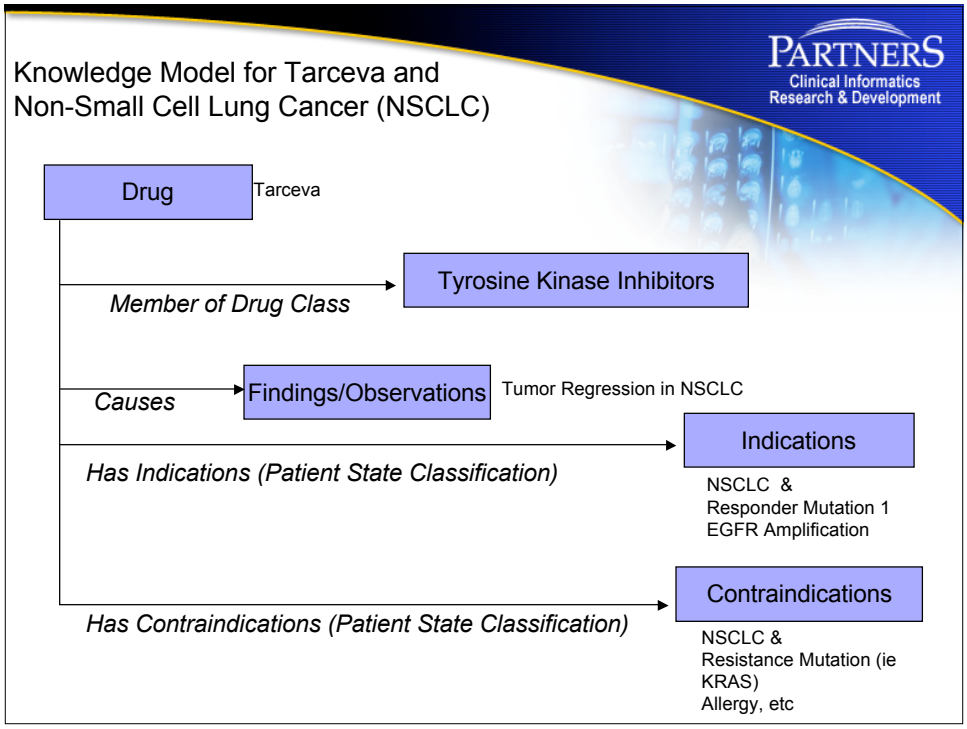
Knowledge Acquisition, Propagation and Change Management

- Our approach is to build a knowledge staging infrastructure that enables knowledge-base change to propagate across related areas,
- Will be leveraging Semantic Web Technologies to deploy knowledge as ontologies in encapsulated, re-usable services to avoid knowledge replication where possible to reduce cost the of maintenance
- EHR vendor community will need to address gaps in their infrastructure approach to knowledge acquisition or it will be impossible to meet requirements of Personalized Medicine


1st Stage Goal Architecture for Knowledge Management
reduce "vertical silos" across multiple applications
Knowledge Management Staging Area
eRoom Content Vetting and Content Editing Portals
Knowledge Search, Retrieval, and Reporting Services
Editors
3rd Party Content NDDF Zynx Micromedex Clineguide Etc.
Validation & Integration
Collaboration Services
Meta-Knowledge
Rules (ILOG), Reports &Queries
Templates/Groups of Orders and Observations
Catalogues (Drugs, Orders, Observations) and Classifications
Drugs, LOINC, SNOMED Terminologies, Prob List Classifications
Documentum Content Management Server
Documentum Deployment Agent
Performance Data Feedback
Research and Reporting Knowledge Repositories
Transaction Knowledge Repositories
Web Service Lookup
Partners Services And Applications
Production Knowledge Bases


Knowledge Model for Tarceva and
Non-Small Cell Lung Cancer (NSCLC)
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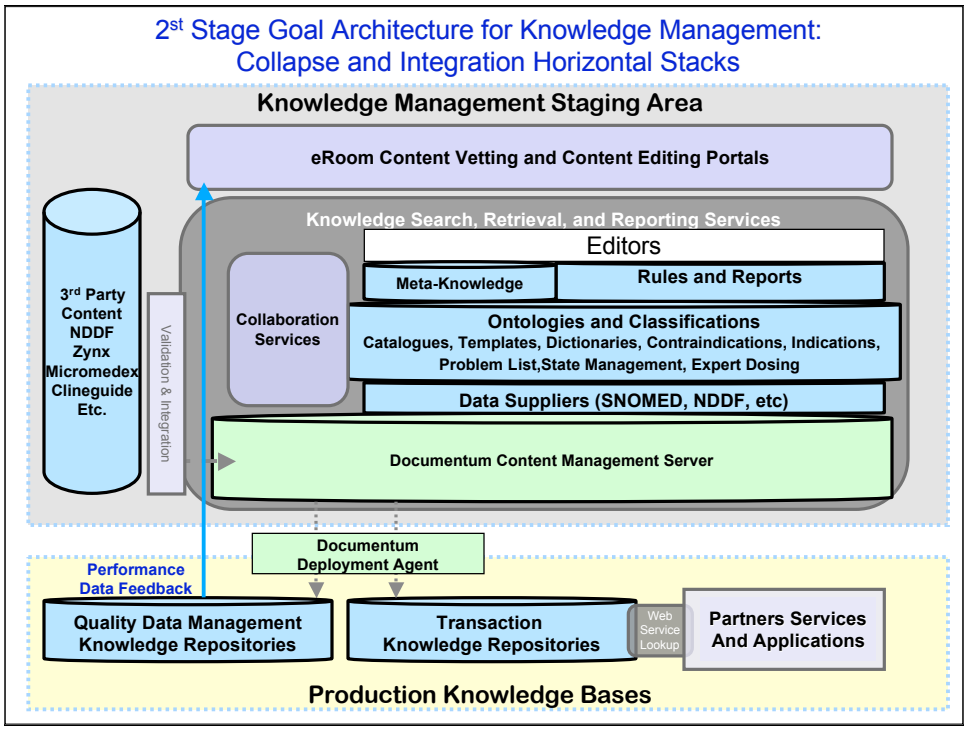
Drug
Tarceva
Member of Drug Class
Tyrosine Kinase Inhibitors
Causes
Findings/Observations
Tumor Regression in NSCLC
Has Indications (Patient State Classification)
Indications
NSCLC &
Responder Mutation 1
EGFR Amplification
Has Contraindications (Patient State Classification)
Contraindications
NSCLC &
Resistance Mutation (ie
KRAS)
Allergy, etc


2st Stage Goal Architecture for Knowledge Management:
Collapse and Integration Horizontal Stacks
Knowledge Management Staging Area
eRoom Content Vetting and Content Editing Portals
Knowledge Search, Retrieval, and Reporting Services
Editors
Meta-Knowledge
Rules and Reports
Collaboration Services
Ontologies and Classifications
Catalogues, Templates, Dictionaries, Contraindications, Indications, Problem List,State Management, Expert Dosing
Data Suppliers (SNOMED, NDDF, etc)
3rd Party Content NDDF Zynx Micromedex Clineguide Etc.
Validation & Integration
Documentum Content Management Server
Documentum Deployment Agent
Performance Data Feedback
Quality Data Management Knowledge Repositories
Transaction Knowledge Repositories
Web Service Lookup
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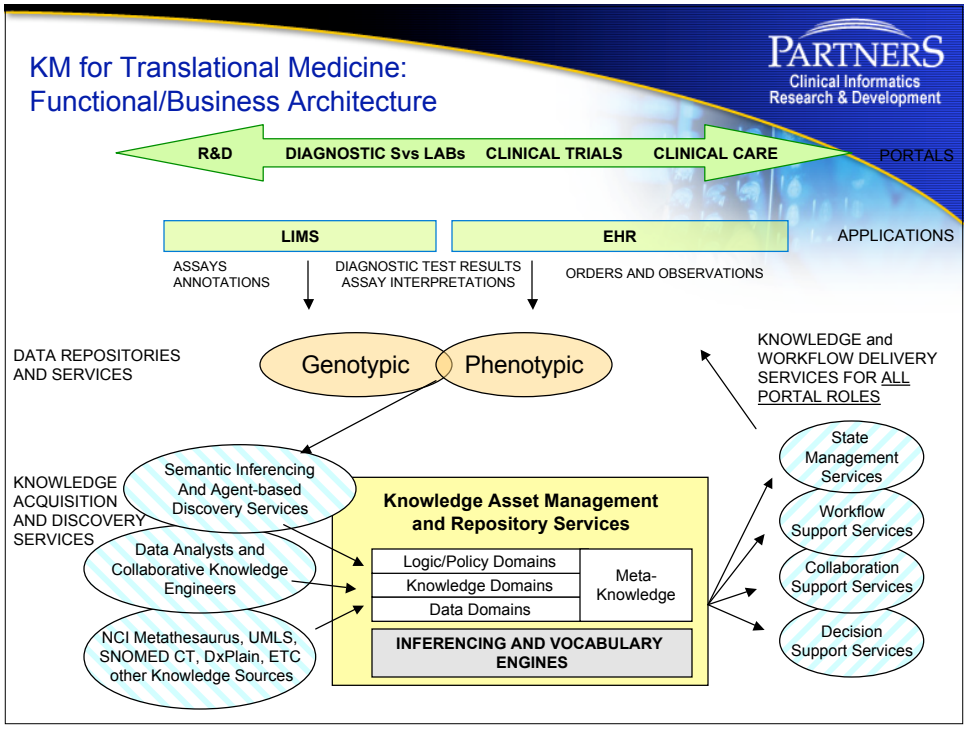
KM for Translational Medicine:
Functional/Business Architecture
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DIAGNOSTIC Svs LABs
CLINICAL TRIALS
CLINICAL CARE
PORTALS
LIMS
EHR
APPLICATIONS
ASSAYS ANNOTATIONS
DIAGNOSTIC TEST RESULTS ASSAY INTERPRETATIONS
ORDERS AND OBSERVATIONS
DATA REPOSITORIES AND SERVICES
Genotypic
Phenotypic
KNOWLEDGE and WORKFLOW DELIVERY SERVICES FOR ALL PORTAL ROLES
KNOWLEDGE ACQUISITION AND DISCOVERY SERVICES
Semantic Inferencing And Agent-based Discovery Services
Data Analysts and Collaborative Knowledge Engineers
NCI Metathesaurus, UMLS, SNOMED CT, DxPlain, ETC other Knowledge Sources
Knowledge Asset Management and Repository Services
Logic/Policy Domains
Knowledge Domains
Data Domains
Meta-Knowledge
INFERENCING AND VOCABULARY ENGINES
State Management Services
Workflow Support Services
Collaboration Support Services
Decision Support Services