Developing a Network to Support Image Data Exchange in Pharma-Driven Clinical Research

A NCI and Novartis Collaboration

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Regulatory Perspective on Clinical Imaging

- "New imaging techniques hold vast potential for use as biomarkers for an array of purposes in product development—measuring treatment efficacy, patient stratification, and improved diagnosis." *FDA, Critical Path Opportunities Report, March 2006*

- "Furthermore, new imaging techniques and imaging endpoints in treatment trials build confidence in the biological rationale as they are often more sensitive than usual clinical measures, thus holding potential for use as biomarkers to measure treatment efficacy. This is particularly important for the development of disease modifying products." *EMEA, Report on Innovative Drug Development Approaches, March 2007*

Pharma Image Exchange Challenge

- Quality Review, Archive
- Method Development
- In-house Analysis, Review
- Problem: Data Access

Background: Pharma Image Exchange Challenge

- **A**

B

- Lots of data, no standard organizing principle
- How to agree on quality?
- Pre-competitive field

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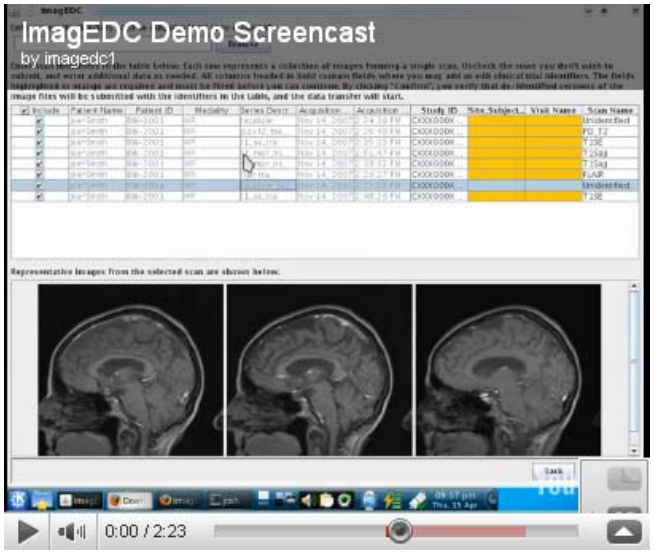
Novartis Approach

- Internal imaging hub
- Proof of concept:
  ImagEDC on caGrid
- Open sourced:
  imagedc.googlecode.com
- To do:
  - Identify an “isolated” process suitable for production use in agreement with small Pharma peer group (shared project?)
  - Implement for productive use
- Outlook: Production use & scale up



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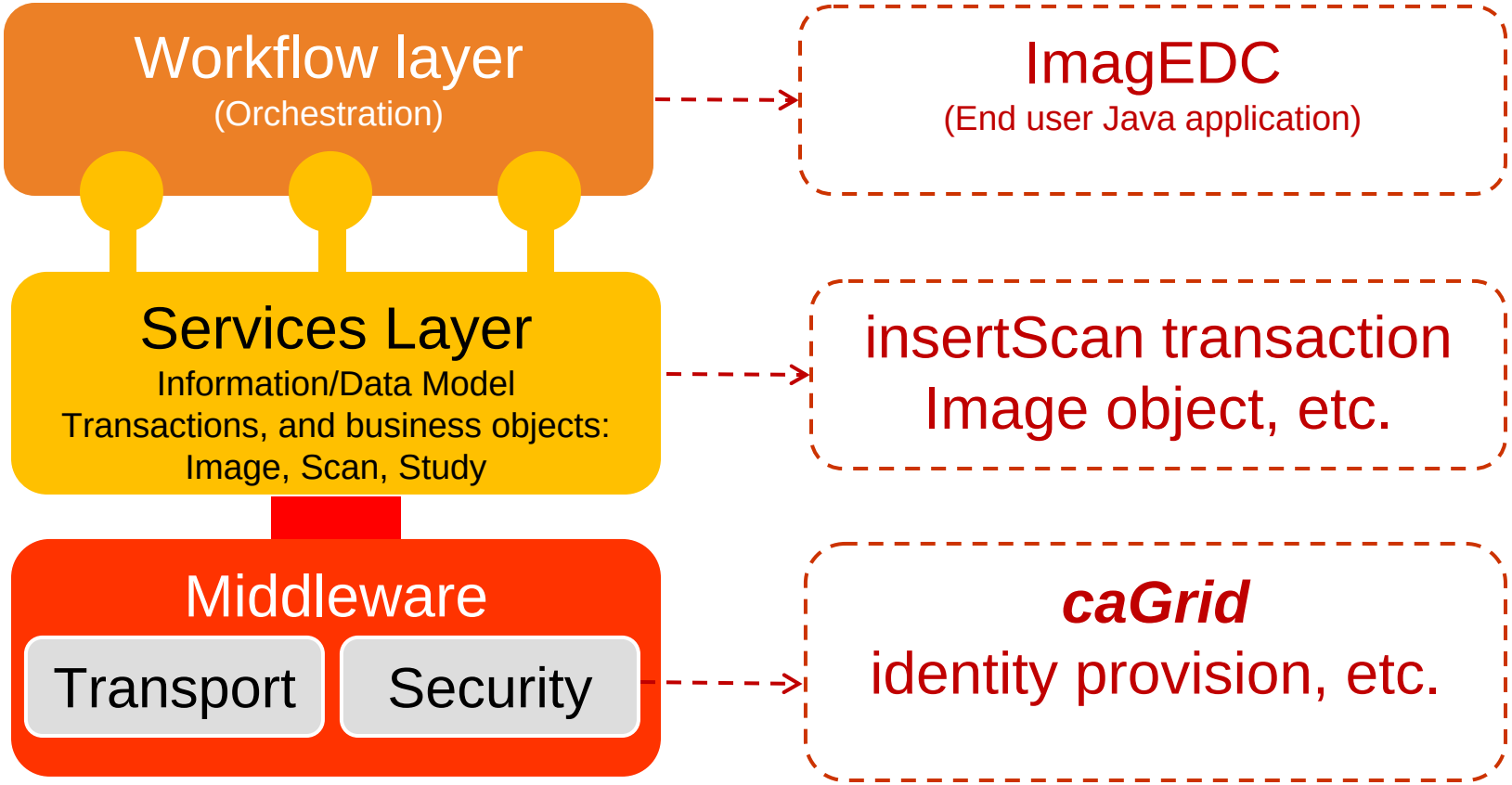
Novartis Approach



- more details: Josh Snyder “ImagEDC” presentation (Wed)

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Bottom Line

- Deliver reference applications & reference processes instead of staying on a more abstract “data standards” level
- Open source as an enabling principle
- Good to speed up innovation process
- And, hopefully, to enable quick adoption across Pharma peers
- Talking with one voice with our partners

Process and Requirements for Production

- Regulations on software code, services hosting
- Ramping up NCI on audit process
- Establishing unified security concept

- Outlook:
  - Agile cycle of innovation, implementation, feedback
  - Add Pharma peers into this cycle
  - Add other tools (backup slide)

Biomedical Collaboration Requires a Complex Ecosystem

Ecosystem Requires Data Liquidity – a "Smart Internet" of Biomedicine -- Among Multiple Stakeholders

- Academe
- Biopharmaceutical Companies
- Consumers
- Diagnostic Companies
- EHR/PHR Providers
- Foundations/Non-Profit/ Advocacy
- Government
- Health Care Providers
- IT Vendors
- Payers
- Personal Genomics Companies
- Venture Capitalists

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There are Huge Data/Knowledge Challenges to Connecting Biomedical Collaborators

- **At present, our data (biological, clinical, lab, pharmacy) are still:**
  - Of varying quality;
  - Non-conformant to standard vocabularies;
  - Frequently incomprehensible or prohibitively laborious to translate from one discipline to another.
- **Unlike almost all sectors in today's knowledge economy, biomedicine has no means for efficient collection, aggregation, integration, analysis, interpretation, and transmittal of data so that it can be converted into practical, useful knowledge by anyone other than the original author.**

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NCI Strategy for Informatics Infrastructure

- **Standards**: NCI works with the community and standards organizations to create standards.
- **Service Specifications**: NCI develops specifications for multiple layers (conceptual model, platform independent model, and platform specific model) for organizations wishing to build or adapt products that can interoperate with NCI services.
- **Reference Implementations**: NCI provides reference implementations of these services with Application Programming Interfaces implemented in many technologies.

Through this strategy, NCI provides the translatable informatics infrastructure on which biomedical innovators can build their own platforms for information exchange. IT vendors can use these NCI IT resources via a non-viral Open Source license that explicitly allows for commercial reuse.

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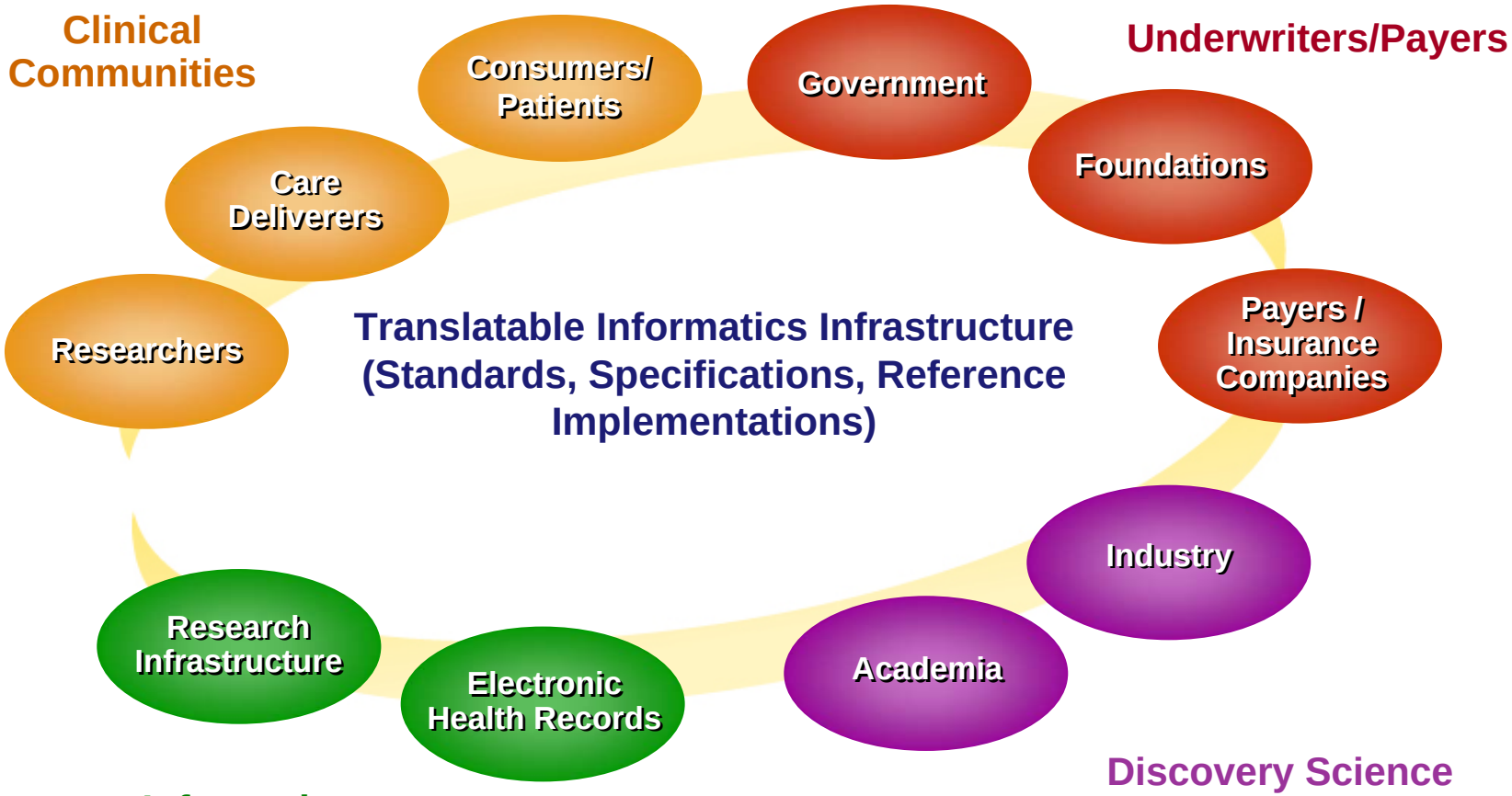
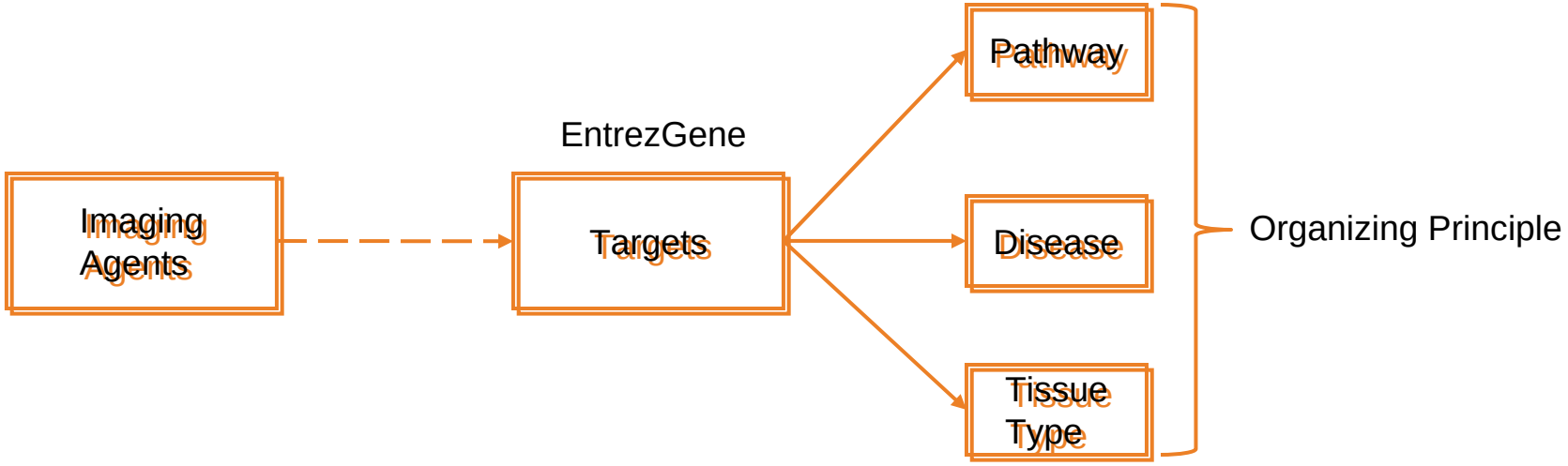
NCI's Translatable Informatics Infrastructure Enables Data Liquidity for Biomedical Collaboration



Backup

RAMP: Organizing imaging data

Another open source effort at Novartis



- Goal
  - Help enable Imaging Scientists to search for relevant tracers by systematically integrating and querying agent, gene, pathway and tissue data
- Example questions
  - What tracers target proteins in mTor Signaling Pathway?
  - What Tissue Type could (*R*)-[^{11}C]RWAY, [^{11}C]RWAY be used as a readout (target – HTR1A, serotonin receptor)?