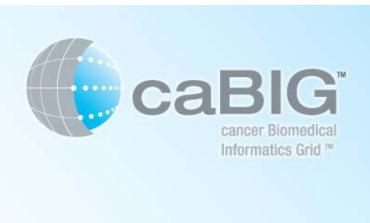# Integrated Enterprise Use Cases

CTMS Face to Face Meeting

8-9 September 2008

Memphis, TN

Source of these Use Cases

- **Each of the use cases was presented to the Domain Workspaces for review and commentary**

- **The resulting material was analyzed and compiled into the set of "integrated" use cases presented here today.**

- **Traceability to the original Workspace comments was preserved, and it recorded in the spreadsheet represented below:**

Levels

Level	Description	Examples
0	**<NEEDED>**	<NEEDED>
0a	**Verbal Communication**	Non-permanent, e.g. verbal communication
1	**Non-electronic data**	Mail, phone
1a	**Non-electronic data**	Paper documents
2	**Machine-transportable data**	PC-based and manual fax, secure e-mail of scanned documents
3	**Machine-organizable data**	Secure e-mail of free text or incompatible/proprietary file formats, HL-7 message
4	**Machine-interpretable data**	Automated entry of LOINC results from an external lab into a primary care provider's electronic health record

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Example Input Requested

Clinical Informatics Use Case: I

- **Clinician sends request for bilateral MRI and biopsy in a patient with a suspicious mass identified in her left breast on a mammogram to radiologist (Level 2)**

- *Is this typical?*
- *How does the request get sent?*
- *Is this a "pain point"?*
- *Is the detail realistic?*
- *What further detail would be useful?*

Clinical Informatics Use Case: I

- **A clinician consents a patient to participate in a breast cancer clinical trial. (Adds at Level 0 & 1a, and several at Level 4)**

- **Clinician sends request for bilateral MRI and biopsy in a patient with a suspicious mass identified in her left breast on a mammogram to radiologist (Level 2)**

- **Patient completes Self-Report for Baseline Assessment using Questionnaire(s) in office/at home (Patient self-reporting is common in population science studies) (Level 3)**

- **Family History obtained in office/at home. (Level 1)**

- **At-Home acquisition of blood pressure, other measurements. (Level 1)**

- **Patient gets scheduled for an appointment at the Imaging Center**

- **Patient goes to an imaging center, and gets an MR image for the lump that might be breast cancer (Level 3, image file) and a stereotactic biopsy of the breast mass is performed**

- **Radiologist report of MRI study is sent back to the clinician (Level 3-4)**

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Clinical Informatics Use Case: II

- Based on integration of population data from cancer registries and EHR's, Clinician knows that late effects are correlated with patient genetic predisposition and specific chemotherapeutic agents.
- Clinician sends patient for a biopsy, biological samples, tissue and serum (May be an image guided procedure, or other type of procedure) (Level 0)
- Surgeon gives sample to the pathologist: Physical or electronic report is given. Sample is received by the clinical laboratory Sample is distributed to pathologist, depending on type. (Level 0)
- Pathologist sends sample to molecular lab service C (Level 0.)
- Lab service runs labs and sends the results back to the pathologist (FSH. IHC, GxP, SNP, et al.). (Level 3-4)
- Pathologist (or clinician, depending on flow of results) collates results from labs and his/her analysis of the tissue, and sends the pathology report back to the clinician (Level 2)
- Results from other analyses (e.g., blood) are sent back directly to the ordering clinician, who collates all ordered analyses

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Clinical Informatics Use Case: III

- Research coordinator uses pathology report and radiology report to determine eligibility. (Adds at Level 0 and several at Level 4)

- Physician uses pathology report and radiology report to make diagnosis, and discusses treatment options with patient (Level 1.)

- There are patient interactive measures which can be used to determine whether a patient wants to take control of their health, or if they want a physician to take control. There are on-line applications and sources to help with collaborative decision making on the part of the patient and physician. (Level 0-3)

- A multi-disciplinary review board reviews the case and makes a diagnosis, and discusses treatment options with the patient

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Translational Research Use Case: I

- Clinical Researcher creates a hypothesis based on bench research, clinical research, and population research (this is from survey of the literature and interactions with colleagues. (Level 1.)

- A retrospective query is performed on a research data repository (with IRB approval if necessary) to determine feasibility of the study.

- Clinical Researcher writes a clinical protocol for validation of a biomarker as predictive of tumor shrinkage in the context of treatment and submits it to the sponsor (Level 3. PDF)

- The protocol is approved and the trial is initiated.

- Patients either apply for a study or are recruited by a clinician.

- Participants are screened on the basis of eligibility. Screening data and sample are supplied to clinic trial coordinator (coordinator) by patient for enrollment evaluation.

- Screening data and sample are supplied to trialist by patient for enrolment evaluation (Level 3 (ex. CRF)).

Translational Research Use Case: II

- Baseline screening is conducted for biomarkers
- Coordinator sends sample to the basic scientist for biomarker screening.
- Basic scientist sends the result of biomarker screening to the trialist (Level 3).
- Need to gather information about the patient and pass it on to the trialist.
- Based on eligibly criteria and biomarker results, the trialist sends the enrolment notification to patient (Level 2.)Typically there would be an interaction with the patient…maybe should say the patients' phsician/trialist is notified that the patient is eligible.
- Clinical coordinator refers patient to radiologist for imaging (Level 1.) Radiologist acquires MR images (Level 3.) Assuming a solid tumor that can be imaged is found. Remove MR..as this may be ultrasound, CT etc.
- Radiologist acquires baseline MR images (Level 3)
- Radiologist analyzes images and creates image annotations (Level 3) and passes along the trialist. Need to put in how the tissue samples are taken. E.g. surgeon flash frozen with liquid nitrogen…..

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Translational Research Use Case: III

- **Clinical trialist collects tissue samples (Level 0) and sends to the pathologist (for diagnosis and for distribution to the basic researcher (biomarker assessment) (Level 0).**

- **Basic researcher runs the biomarker assays and sends analysis results (Level 3) to trialist**

- **Lab technician runs the biomarker assays for the basic researcher, and reports results back to the trialist (possibly via the basic researcher)**

- **The pathologist sends staging and grading to the trialist (Level 2) (This is repeated throughout the study)**

- **The pathologist assesses the tissue specimen and sends results to the trialist (This is repeated throughout the study)**

- **The trialist starts the treatment, and the cycle of MRI image collection and annotation and reporting, tissue collection and molecular data collection continue throughout the trial, and all information is sent back to the trialist throughout the duration of the trial (Level 3)**

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Translational Research Use Case: IV

- **The trial closes and ends, and all the data are provided to the statistician, (Level 3)**
- **Statistician communicates the clinical significance of and evidence for biomarker response prediction (Level 3)**
- **The statistician, approved by the clinical trialist, sends the report to the sponsor (Level 2)**
- **Trialist, basic scientist and statistician write a scientific paper reporting the results (Level 1)**
- **Data goes back to the sponsor (Level 3)**

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Next Steps

- **Creating a detailed set of use cases, with controlled terminologies, a fully-defined set of actors and complete semantics/syntactics**

- **Integration into ongoing intra-Workspace integration activities such as CTMSi and ICRi**

- **Identification of key transport layer mechanisms for data integration**

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