caBIG Radiation Oncology Enterprise Use Case

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ATC • AdvancedTechnologyConsortium
Providing support in quality assurance and data management for radiation therapy clinical trials

NATIONAL CANCER INSTITUTE

Acknowledgments: Use Case based on efforts of many groups

- caBIG TCons: QARC, ACRIN, ITC, Ohio State/Emory
- Case Review Forms: RTOG
- NBIA RTOG 0522: RTOG, ACRIN, ITC, RPC
- QRRO (**Q**uality **R**esearch in **R**adiation **O**ncology)

RTOG
RADIATION THERAPY ONCOLOGY GROUP

QARC
Quality Assurance Review Center

Image-Guided Therapy Center
An Advanced Technology Clinical Trials QA and Support Center

RPC

ACR®
AMERICAN COLLEGE OF RADIOLOGY

QRRO™
QUALITY RESEARCH IN RADIATION ONCOLOGY
(formerly Patterns of Care Study)

Proposal to caBIG

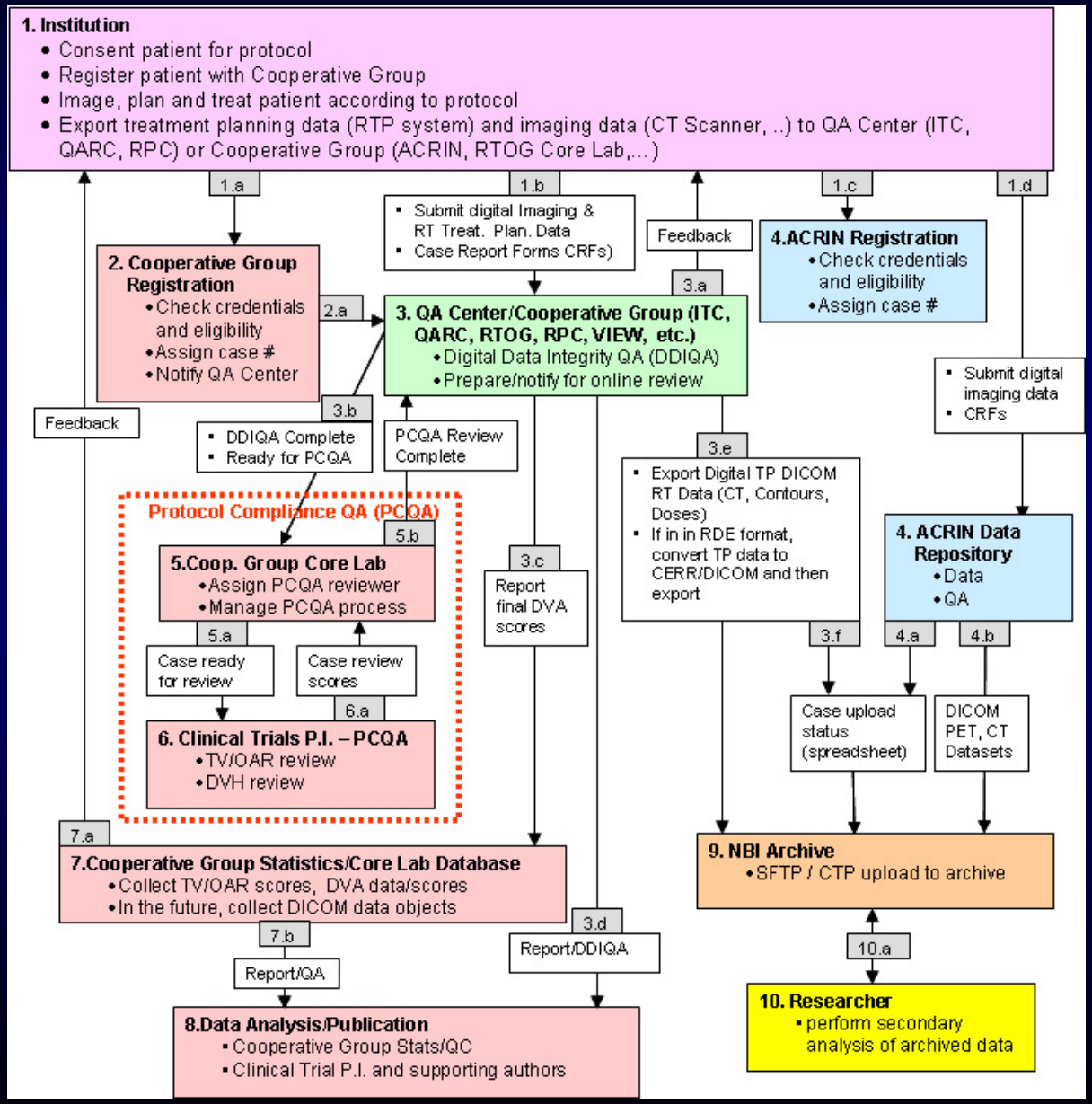
- We (ATC and collaborators ACRs QRRO) wish to engage the caBIG Imaging Workspace and the Clinical Trials Workspace to join in a Phase 1 project to demonstrate the use of caBIG software tools to support active Radiation Oncology clinical trials.
- Specifically, to develop the connectivity between the various treatment planning systems and the patient information systems in the radiation oncology department's EMR and the hospital EMR including pathology, laboratory, radiology, and other important measures.

Radiation Oncology Enterprise Use Case

https://wiki.nci.nih.gov/display/Imaging/Imaging+Use+Case+-+Cooperative+Group+Support

caBIG Use Case Data Flow

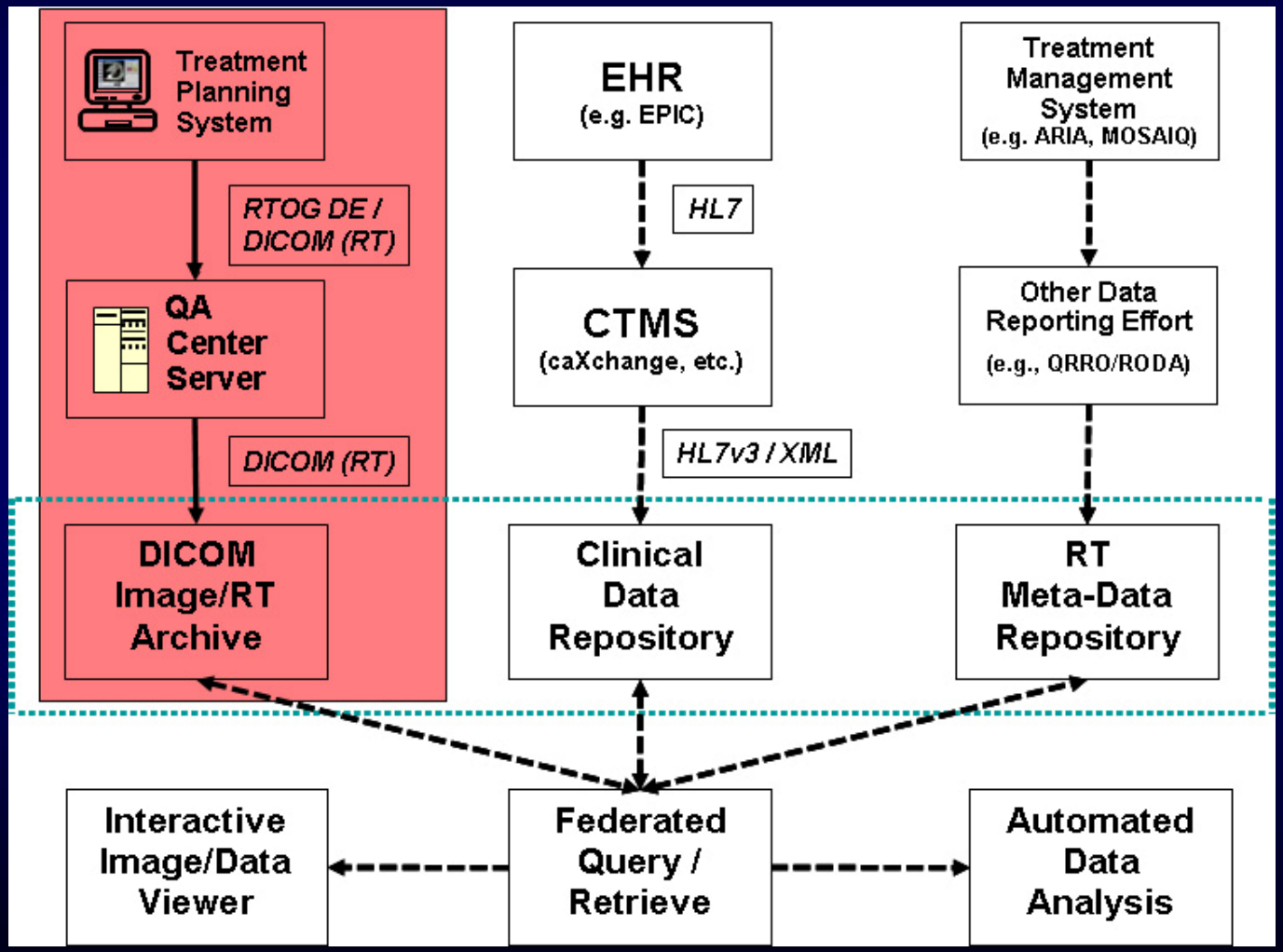
- Modeled after RTOG 0522 / ACRIN 4500.
- Need to identify caBIG tools and infrastructure that can aid in data collection, QA, and analysis.
- Applicable to both RTOG and QARC (VIEW) supported clinical trials



Radiation Oncology Use Case

- Extend Use Case to include on-going collaborative activities:
  - especially the ACR's QRRO project
  - industrial collaborators associated with radiation oncology to reach into community electronic medical record (EMR) systems across U.S. and remotely retrieve key quality of care information.

ATC (RTOG, QARC, ITC) | ***caBIG*** Imaging/CTMS | ***ACR/*** QRRO



- Demo-graphics
- Diagnostics
- RT Course
- Lab Values / QoL
- Tumor Prognostics

Radiation Oncology Enterprise Use Case

- The EUC is intended to give a “Big Picture” of the various actors involved and the data flow in the current radiation oncology clinical trial paradigm.
- Data flow depicted is not intended to be specific to any QA Center or to be cooperative group centric
- Represents a real world case that would facilitate the development of a plan of action to implement caBIG tools at key points in the clinical trial process
- More limited scope Use Cases can be developed form this EUC document.

EUC: Relevant Actors

- Actor 1: Government or Industry Trial Sponsors
- Actor 2: Cooperative Group (RTOG, COG, CALGB, SWOG, EORTC,….)
- Actor 3: Industrial vendors:
- Actor 4: Participating institution (radiation oncologist, physicist, dosimetrist, CRA,):.
- Actor 5: QA Center Personnel (Physicians, CRAs, physicists, dosimetrists, computer specialists).
- Actor 6: Cooperative Group Statistician and Clinical Trial P.I. and supporting authors.
- Actor 7: NBI Archive.
- Actor 8: Researcher (physicians, physicists, computer scientists, biologists).

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- National Biomedical Imaging Archive (NBIA)
  - a key component of this use case.
  - DICOM RT and CT images can be sent from multiple locations, with patients being mapped to a common Patient ID structure, and stored in a central location.
  - images can then be queried and downloaded directly through the web application interface or via federated grid queries over NBIA's grid API.
  - This has already been tested in the current version of NBIA as a proof of concept.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- Annotations and Imaging Markup (AIM)
  - purpose is to develop a standard for medical image annotation and markup for images used in research space, and image based cancer clinical trial.
  - a rich amount of image metadata is recorded in radiation treatment clinical trials.
  - AIM extensions could record the critical information from CT for treatment planning.
  - AIM-compliant workstation could be used to annotate structures on images used to plan the treatment, such as the contours of all protocol required organs at risk, GTV, CTV, and PTV.
  - AIM annotations could be uploaded to an AIM server providing federated AIM queries.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **eXtensible Imaging Platform (XIP): Trial-specific customized workstation**
  - consists of a set of tools for rapidly developing medical imaging processing and visualization applications.
  - One of the goals for XIP is to allow cancer researchers to easily create complex data analysis programs (e.g. lesion change detection) targeted at specific investigations.
  - By employing the coming DICOM WG-23 Application Hosting interfaces, XIP applications can be distributed to a variety of installations, thus providing some consistency in data collection for clinical trials.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **eXtensible Imaging Platform (XIP): Trial-specific customized workstation**
  - Overall usefulness of the tool for radiotherapy clinical trials depends on the support for reading and rendering of DICOM RT data in the XIP Scene Objects.
  - Of particular importance is the segmentation information conveyed in the RT Structure Set IOD.
  - Implementation of the DICOM WG-23 Application Hosting Interface in radiotherapy treatment planning system software would also be helpful, but it is unclear whether vendors have any incentive to provide such a feature.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **Middleware: Grid Connectivity (caGrid and/or stand alone)**
  - The In Vivo Imaging Middleware (IVIM) comprises a series of services and extensions to the caGrid middleware tools.
  - IVIM includes a DICOM data service for grid based access to DICOM PACS, a generic image data service to store generic image data types.
  - services allow a user to query, retrieve and submit.
  - Includes VirtualPACS, a grid client application for the DICOMDataService.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **Middleware: Grid Connectivity (caGrid and/or stand alone)**
  - VirtualPACS appears as a PACS server to a DICOM workstation and acts as a middleman that allows the workstation to interact with DICOM grid services.
  - Middleware infrastructure also includes the AIM data service (AIME) designed to support grid based storage, retrieval and query of AIM annotations.
  - AIME works along side NBIA and other image archive or PACS services.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **Algorithm Validation Toolkit (AVT)**
  - AVT is a toolkit for building study-specific or trial-specific tool suites for statistical analysis of sources of variation.
  - AVT is built in large part out of XIP technologies, runs in the XIPHost application framework, and incorporates AIM and R (statistics package) libraries.

Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **Cancer Central Clinical Participant Registry (C3PR)**
  - web-based application used for end-to-end registration of patients to clinical trials.
  - includes capturing the consent signed date, eligibility criteria, stratification, randomization, and screening.
  - Clinical workflows are enabled by both subject- and study-centric views into the registration process.
  - can be run in a standalone mode where study definitions, investigators, study personnel, and sites are entered into the system, or C3PR can be run in an integrated mode with the caBIG Clinical Trials Suite (CCTS).
  - C3PR also enables multi-site clinical trials where registration information is entered locally at affiliate sites and the registration is completed by call-out to the coordinating site.

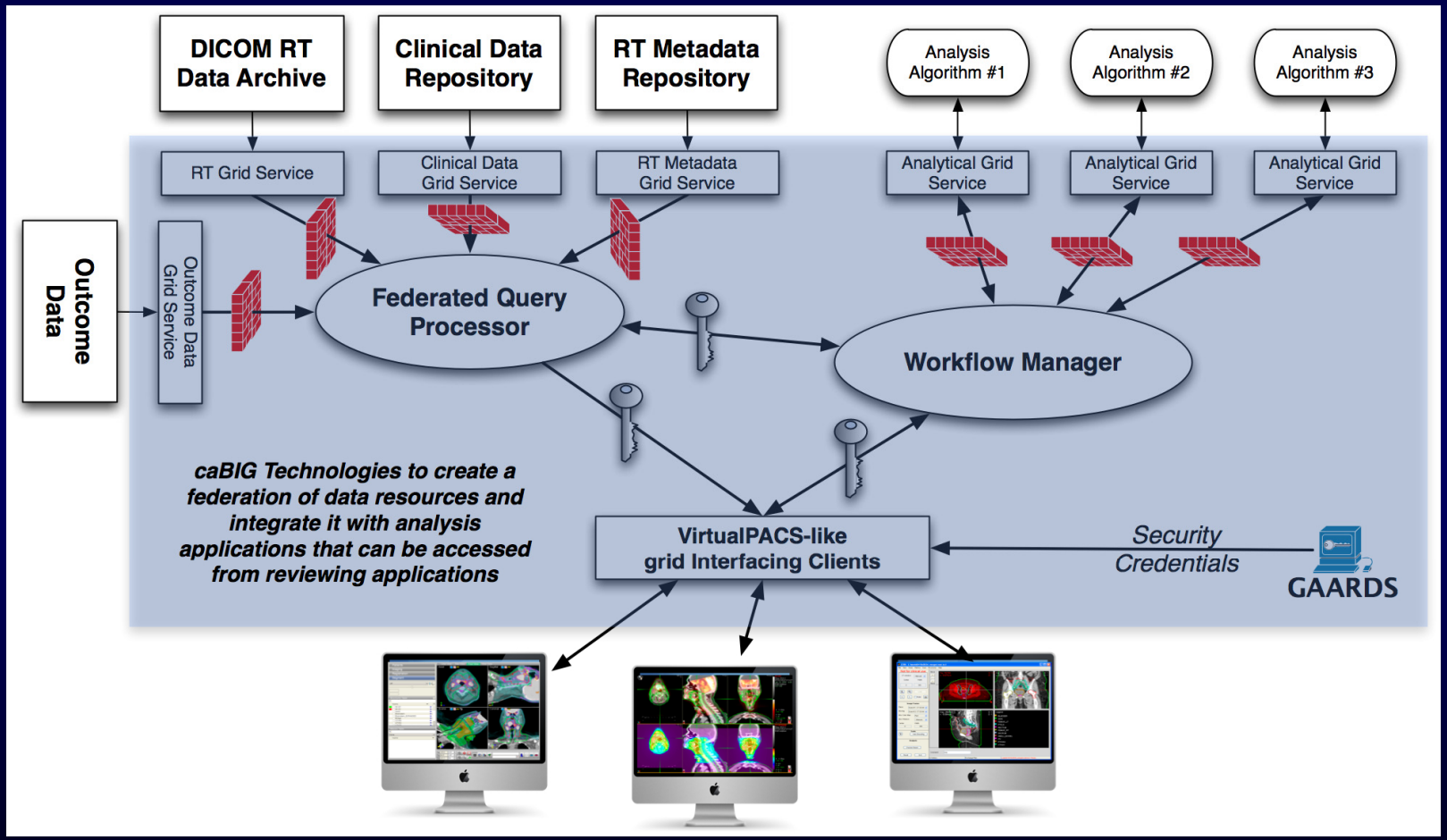
Existing caBIG tools, data sets, etc. that can be utilized to support the use case

- **Patient Study Calendar (PSC)**
  - an open source, standards-compliant software application intended for use by organizations that manage patients on clinical trials.
  - PSC is a web-based application providing the ability to create and edit study calendar templates, generate and view prospective calendars of patient activities, track activities as they occur, and manage patient calendars as they change during a study.
  - PSC accommodates all types of studies and facilitates management of the screening process, registration, active monitoring, and long-term follow-up.
  - PSC supports multi-site environments as well as the ability to share templates between instances of PSC.

caBIG Radiation Oncology Enterprise Use Case
Summary

- Use Case lays the groundwork for developing a testbed for real-world evaluation of caGrid-based tools for supporting RT clinical trials.
- Substantial development effort is required in moving from demonstration to production software that can be reliably adopted for support of RT clinical trials data collection and analysis.
- Tool evaluation in a near-production environment will serve to check assumptions of design/development team and expose problems that cannot be anticipated.
- Such translational testing is needed to facilitate adoption of caBIG tools for production use in clinical trials.

Architecture of a caBIG enabled system to support RT based clinical trials



Architecture of a caBIG enabled system to support RT based clinical trials

- Grid data services to enable the sharing of DICOM RT Objects, clinical data, outcome data, associated RT metadata and any annotations and markup created by reviewers.
- could build upon the work that has already been done by members of the Imaging workspace in the CTTI project (design of a grid enabled MAX archive, and grid archives for CERR objects), IVI middleware and AMIE (The AIM Data Service developed by Emory).
- These grid services would also require mechanisms to support role-based data access controls that utilize grid credentials.
- In addition, it is anticipated that AIME would need to be extended to accommodate extensions of AIM used to describe RT metadata (see item 2 below).

Architecture of a caBIG enabled system to support RT based clinical trials

- Information models to better describe the data that is being shared on the grid. This includes AIM extensions to support RT use cases, extensions to the NCIA DICOM data model to support DICOM RT Objects and models to describe outcome data.
- Grid analytical services to support on-demand deployment and invocation of review and analysis routines for RT use cases.
  - This work can greatly leverage the XIP platform to build new or reuse existing analysis applications and IVI middleware tools such as dynamic service deployment.

Architecture of a caBIG enabled system to support RT based clinical trials

- Grid middleware that federates the various data services allowing exploratory queries that span multiple data models.
  - build upon federated query processor and query execution work that was done in the QueryFormulation project.
- Workflow execution framework allows researchers to obtain data from the federated data services, discover analysis algorithms relevant to the trial or the data archive, construct and execute a workflow of the various analysis routines.
  - workflow could also involve human participants. Therefore a central review protocol in a trial involving multiple human reviewers would also fall in this category and this workflow execution system will create and manage worklists that distribute and stage data to the reviewers and collect their findings.

Architecture of a caBIG enabled system to support RT based clinical trials

- Interfacing clients, similar to virtualPACS that allow existing remote review clients to interact with the various grid services with minimal code change.
  - work will build upon the work done in the CTTI project (grid enabled CERR).
- Deployment of the caGrid security infrastructure (GAARDS) and integration with the institutional identity providers of the participating institutions.
  - Activity will also result in a best-practices document which documents the security policies that should be followed when using grid and SOA technologies to support clinical trials.