IHE-RO Strategy Meeting
Shands Cancer Center, Gainesville, FL
3-4 March 2011

Attendees:

Ramesh Rengan, Co-chair, UPenn
Charles Able, Wake Forest
Bruce Curran, TC co-chair, Brown U
Michael Hagan, RadOnc, VA
Anh Le, Post-doc, UFl
Barbara Muth, Research Dir, ASTRO
Jatindar Palta, Co-chair, ASTRO TF
Kate Dodd, Marketing, ASTRO
Colin Field, Co-Chair, Cross Cancer Center
Mika Miettenin, Co-chair, Varian
Barry Asch, Administrator, Moffitt CC
Rishabh Kapoor, IHE-RO TManager, UFl
Jim Percy, Marketing, Elekta TPS
Daniel Yeung, Physicist, UFl
Sidrah Abdul, IHE-RO Support, ASTRO
Craig Stevens, RadOnc, Moffitt CC

ACTION ITEMS

DUE DATE	TASK	ASSIGNED TO
Completed	Purchasing of IHE-RO.net domain, one stop shop for IHE-RO (add link to EORTC, CARO, AAPM)	Curran
March 8 (PRO draft), March 31	User friendly IHE-RO message, PRO article using new vocabulary, IHE-RO compliance	Rengan, Field, Curran (to physics world) et al
March 10	CMS Town Hall Meeting- IHE-RO Presentation to FDA	Palta
March 11	HL7 Use Case: EMRs, scheduling, billing use case Mika's use case for Total Profile	(Kapoor, Stevens, Yeung) Miettinen, Curran
March 11	Send new roster list to Curran, Tripuraneni, Rengan	Abdul
March 15	Text for purchase specification/RFP (document revised by Mika)	Able, Miettinen
March 15	What is IHE-RO product compliance	Curran, TC
March 18	Letter to thank volunteers	Rengan, Stevens, Abdul

March 18	List of SCAAROP members to Rengan	Muth
By end of March	Communication to physicians and global community	Albuquerque, Asch, Vendors
May 1 (to present at ASTRO June Board meeting)	IHE-RO Business Plan	Dodd, Abdul, Muth, Curran, Palta, Rengan
May 17	PC Subcommittee to define clinical compliance	Curran
June 3	Grant Development	Palta, Rengan, Field, Stevens, European contact
August 15	IHE-RO compliance web based application to support purchase specifications	Yeung, Le, Kapoor, ASTRO
October 2-4, 2011	Presentation and booth at SROA meeting	Rengan, Asch, Able?

Introduction:

Ramesh opened the meeting and gave a framework for our discussions. How do we (1) make IHE-RO a necessary request of our colleagues in purchasing decisions, (2) translate the techno-babble that is necessary to IHE-RO functioning to issues that make sense clinically, and (3) market the utility of this approach to all (vendor and customer).

One example that was brought up was the issue of determining previous treatments in response to the need to re-treat.

Problem Definition:

Some questions:

- Who are the end-users?
  - Different messages for different end-users
    - Medical Physicists
    - Radiation Oncology Admins
    - Rad Onc end-users (other MDs, referring doctors)
    - Upper-level Admins / Purchasing Agents
  - Messages for upper-level admins as to why it is important to the hospital!
    - Throughputs are often a key message that needs to be put forth
    - Simplicity is also important to many of the end-users
- What tools are the most useful?
  - RFPs are useful, but not used in a majority of clinics
  - Purchase order template
- How does the vendor demonstrate IHE-RO compliance?
  - Pass Connectivity Testing

    - Within 1 year, release clinical product (there are currently 4 products in the market that can show "IHE-RO compliance."
    - Verify Connectivity testing on clinical release
        - Test Tools used by RPC?
        - PC sub-committee (chaired by BHC)
            - Add vendor reps
            - Way to channel user feedback from field
            - Issue tracking
    - Needs to be clinical capability specific
- What equipment should we be focusing on?
    - TPS
    - Linacs
    - TMS
    - QA Devices
    - Imaging Software
    - EMR

Some deliverable ideas:

- What does IHE-RO offer the practioner?
- Requirements for IHE-RO should not be optional, not allowed to have only a partially safe car. How is compliance determined?(ACR Accreditation?)
- Better message, particularly more clinically relevant to the end-users.
- Identify deliverables.
- How do we sustain IHE-RO!
- How do we get the manpower to get these actions accomplished in a timely fashion.
- A commitment to maintenance.
- Be careful what you do, as others may grab without concern (regulatory, Chinese)
- Could we develop the test tools to allow clinical users to test compliance.
- Is the current structure limiting IHE-RO, profiles rather than performance & Features.
- Develop IHE-RO interactions with other ASTRO and professional society activities.

FDA Webex:

Call-in Attendees: Cindy Tomlinson, Peter Balter, Kevin Albuquerque, Rene Valasquez, Bob Pekarek, Juan Carlos Celi, Steven Sutlief, Jarod Finlay, Jeff Yue, "Tomotherapy" (room of people, including Eric), Todd McNutt, Andras Szentmiklossy, Carnell Hampton, Stuart Swerdloff, Emily Wilson, Yan Yu, Stephen Vastaugh.

Cindy T. , Mgr of Regulatory affairs for ASTRO, led the discussion. The focus of the discussion was to discuss ASTRO interests with the FDA which resulted in a meeting with the FDA last week. From FDA, there was a large group. ASTRO led by discussing the Target Safely (TS) Program developed by ASTRO. They discussed the 6 points of the TS campaign, which includes IHE-RO. The FDA discussed the new 510(k) program changes, including a network of experts, a public database, and the IOM report. Regarding IHE-RO, the discussion encompassing how devices work within systems, historically, devices were engineering specific, need today for more interdisciplinary approach. They would like a continuing dialog, including a workshop between IHE-RO, ASTRO, and FDA. This meeting is under development. The goal would appear to review how we review products and what benefit FDA could acquire from using this information.

One question was whether the FDA is planning on looking at the clinical rather than the manufacturing side. There is clearly interest here, but they were very guarded in their response. FDA has clearly looked at devices in isolation, but venues such as IHE-RO could help to look at a broader, clinical picture. Many of the questions on connectivity will depend on the IOM report, not really addressed in the IOM charge, but perhaps will come from the IOM.

There was a discussion on how safety can be integrated. The HIT Committee (chaired by BHC) could also be used to satisfy this. ACR accreditation might also be used to review and establish this. One has to be careful not to overstep the IHE-RO charter. However, it should be an ASTRO initiative.

Problem Definition / Solutions:

Mika led this discussion. He started with a slide showing a simplified connectivity for a standard rad onc core work/date flow. Some entities (VSim/TPS. OIS, TDD) may share databases, etc, but his premise is that nothing is, of yet, "IHE-RO Compliant".

In looking at IHE-RO Integration Profiles, we have accomplished good work in Contour exchange, Plan exchange, Dose Display, and Multi-modality Image Registration. He noted that, in the new workflow profiles, data content is ambiguous, which can be construed as a patient safety issue.

He then showed a different view of our profile successes. He noted that in the complete flow, the TMS is a producer of plan data, in that it re-produces a plan when sending it to a TDD.

The TC should create a modified Integration Profile that re-uses all the ARTI transactions to include the TMS as a Producer and the TDD as a consumer in order to show vertical (e.g. clinical path) integration rather than plan sharing. This should be a pretty simple profile development, really only affecting Volume 1. We may want to add some additional actors (i.e. a FFF producer/consumer and a 'scheduling plan producer/consumer).

Deliverables & Approach:

- Improved Success Tables (Mika's Vertical Integration Tables)
- Application that interacts with user to determine needs
    - End-User requirements
    - Equipment of interest
    - Generates relevant profiles, actors-of-interest, potential vendors
    - Appropriate / necessary options, (serial # passed?)
- What is IHE-RO Compliance?
    - Pass a Connectathon
    - Release the product within 1 year
    - Verify that the clinical release of product
        - How? Use of test tools by Radiological Physics Center
- Presentation of sample RFPs by Mika showing general levels of detail
- Kate then presented on some proposed IHE-RO Marketing ideas
    - Know your audience (discussed earlier this morning)
    - Speak to them (our discussion on clinical vs technical terms)
    - Recognizable (consistent presentation / recognition)
    - Easy to find
    - Benefits to the recipient
- Action Items
    - Grab Websites for ihe-ro.org and ihe-ro.net (.org ones are taken)

- 2011 ASTRO Annual Meeting Product Theater
- Directed lecture @ SROA / Booth / SROA-oriented Product Theater
- Video Tutorial on IHE-RO and the RFP process
- Could the Test Tools be a clinician-usable product?

Review / Homework:

- Application to support RFPs (Yeung, Le, Kapoor, ASTRO, Vendors)
- Text for RFP/PO (Able, Mika)
- Clear definition of IHE-RO Clinical Capability Compliance
  - Curran to organize group to determine how to define clinical compliance. Goal for report is 5/15/2011.
- Communication to MD and Global Community
- User friendly IHE-RO Message
- IHE-RO requirements not optional
- Message to FDA- identify appropriate people for workshop
- IHE-RO.NET
- IHE-RO Sustainability
- Clinical feedback- moderated listserv? Issue Tracking. The group had some concerns that it should not be a "help desk" for product questions. It should serve as a hotline for reporting only.

Business Plan:

- What is our mission statement?
- Vision Statement?
- How do we sustain IHE-RO?
  - Projects
  - Finances
    - Annual Budget is about $300k, funded by ASTRO and Vendor Tools
    - Test tools largest budget item (~$160k)
    - Fee for service model re IHE-RO testing / compliance
    - Could we include an IHE-RO earmark in Corporate Dues
  - IHE-RO Grant application on behalf of ASTRO
    - ROI-based
    - PC Research Committee (Palta, Rengan, Field, Stevens, EU contact)
    - By June (NIH-based Safety Grant)
    - ESTRO, Canada
    - Curran involved as sub-con
  - Stakeholders
    - Volunteers, letters of acknowledgement (Palta, Muth, Abdul, Curran)
    - Letter to thank volunteers (Stevens, Rengan, Abdul)
  - Challenges
    - Funding for PC meetings
    - ASTRO IT/MedPhys support
- Short Term Goals
- Long Term Goals

Resolution and Wrap-up:

- FDA Message (3/10)
  - Palta to give overview to FDA next week (5 minute) to put info on record
- Communication to Physician and Global Community
  - Cost/benefit of IHE-RO (Kevin A., Barry, vendor mix)
  - Financial Analysis
  - What's in it for them
  - Risk of not participating
  - Must be working to expand to outside world!!!!!!!!
  - Build HL7 team for scheduling, demographics, and Rad Onc support
- Use Cases
  - HL7 Use Cases
  - Mika's Total Process
  - European Involvement
- Outstanding Actions
  - Business Plan (Dodd, Muth, Abdul) 6/1
  - IHE-RO Compliance App (Yeung, le, Kapoor, ASTRO) 8/15
  - What is IHE-RO Product Compliance (Curran, TC) 5/15
  - Text for Purchase Spec (Able, Miettinen) 3/15
  - Connectivity Problems (3/11)
    - HL7 Use Case (Kapoor, Ent Scheduling Use Case)
    - Mika's Use case for Total Profile
  - Communication
    - to FDA (Palta) 3/10
    - to MDs and global community (Albuquerque, Asch, vendors) 3/31
    - User-Friendly IHE-RO Message (Rengan, Field, et al) 3/8, 3/31
    - IHE-RO.net
    - SROA Presentation (Able, Asch) 10/2/2011
  - Grant Development (Palta, Rengan, Field, EU, Stevens) due June