Informatics infrastructure (Mr Avila and Mr Buckler)

- Mr Avila reviewed progress in the ad hoc group on data resources which met for the first time in week of Jan 18, 2010.
  - The ultimate goal is to facilitate the building of large public databases for research
  - The group aims to identify issues and solutions to accelerate development of open databases
  - Would like to explore compiling data from existing clinical trials, as well as evaluate what has worked/didn't work in the past
- Mr Avila reviewed experience with Give a Scan with the Lung Cancer Alliance as an example
  - Patients are directed to tools to anonymize scans; anonymization is a critical issue
  - Mr Avila’s group accepts the data for curation using the open source MIDAS tool
  - The curation process is cost-, labor- and time-intensive.
- Interest in application of AVT as it presently exists to analyze 1A data as well as to envision an improved AVT, NBIA, AIM
- caBIG has interest in supporting informatics extensions and may be able to offer support to QIBA
  - caBIG is linking images to standardized vocabulary databases
  - caBIG tools and software are all free, open-platform, open-source and distributable
- The first level of activity is supporting clinical trials and research activities; next level will be dissemination into clinical practice, e.g. structured reporting, with controlled vocabularies, automation and harmonized with quantitative imagine readouts
- The RSNA has an active committee on structured reporting which has posted structured reporting templates
  - The RSNA 2010 Quantitative Imaging Reading Room will also feature structured reporting
- QIBA Profiles will have semi-standardized, modular portions which may be used in multiple profiles
- Dissemination strategy needed to get structured reports into the radiology community
Emerging Roadmap

- Following discussion with Federico Goodsaid at FDA, a number of steps in the process to qualify imaging biomarkers have been outlined (see attached document)
- The engagement process with FDA is initiated with a Request Letter from a consortium such as QIBA; subsequent steps include preparation of a Briefing Document and a Full Data Package
  - The steps are well-aligned with the European ‘Advice’ processes
- Mr Buckler reviewed the Table of Contents of a sample Briefing Document, to include:
  - Literature review (completed with *Annals of Oncology* submission)
  - Data (e.g. data from Groups 1A-B-C, Volcano; work of this QIBA collaboration)
  - Retrospective analysis of existing clinical data; reinterpreted based on new biomarker (examples presently underway under the auspices of QIBA)
  - Plan for collection of future data, e.g. Roadmap
- Consider performing a mock / internal test of the process to insure all pieces complete

Next Steps

- Continue discussion on the Roadmap draft and submission to FDA
- Continue framing of QIBA activities and outline of QIBA process