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Quantitative Imaging: Building the Foundations

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Note :

RSNA recently announced an additional $1.27 million of funding from the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to support research by the Quantitative Imaging Biomarkers Alliance (QIBA). The funding will be used towards the development of a Quantitative Imaging Data Warehouse, research to characterise the sources of bias and achievable precision associated with quantitative imaging, and to further develop and test phantoms and digital reference objects.

The Quantitative Imaging Biomarkers Alliance (QIBA) was set up by the Radiological Society of North America (RSNA) in 2007 to unite researchers, healthcare professionals and industry stakeholders in the advancement of quantitative imaging and the use of biomarkers in clinical trials and practice. HealthManagement spoke to QIBA's Chair, Professor Daniel Sullivan, about QIBA's progress.

What are the current priorities for QIBA?

Our main priority is developing QIBA Profiles. A Profile consists of one or more claims, which tell a user what quantitative results can be achieved by following the Profile. The details tell a vendor what must be implemented in their product; and tell a user what procedures are necessary. QIBA is working on finishing up Profiles from those committees working on them.

QIBA also works on compliance checklists for manufacturers and vendors. With a scanner manufacturer, for example, the simplest and easiest way to achieve compliance is to have self-certification, as against test objects and phantoms. That way engineers at the factory can run those tests to see if their machine meets specifications. This is a straightforward process for reproducibility. For an individual scanner the physician or physicist can do this test on their own site. We are also looking at this process being part of site compliance. We anticipate that most current scanners will be in compliance. However, there is an installed base of older scanners in the U.S., and many of these will not comply. The compliance process will need a test set of cases, and the challenge is to get a representative set. QIBA would like this process to be part of an existing cer tification scheme, such as the American College of Radiology Imaging Network (ACRIN™)'s scheme for clinical trials accreditation. There have been preliminary discussions.

In general QIBA is continuing to obtain data about precision for all modalities so that we can get reproducible measurements for all modalities. Collecting data to understand reproducibility has not been well studied or evaluated.

What role will quantitative imaging play in clinical practice in future?

The overarching issue for all physicians is the flood of information they have access to, more than one person can deal with, for example from electronic health records, decision support systems and appropriateness criteria. Ideally, all of these systems need objective data. Qualitative reports do not lend themselves to objective data. As physicians more and more expect information to be quantitative and objective, they will demand more of these data from imaging. In addition co-payers will need this kind of information.

Does QIBA facilitate reporting of errors/ variability currently?

Not currently, as the Profiles have not yet been disseminated into clinical practice. They could play such a role in the future, but would need to be more widely disseminated. Third party payers might collect such information. There is little incentive for radiologists to collect such information at present.

Please tell us more about the Uniform Protocol for Imaging in C linical Trials (UPICT) t hat QIBA has developed.

This is for use in clinical trials. The idea behind it was to improve consistency of data across multiple sites. Consistent and reproducible numbers within a specified range result from a QIBA Profile. The UPICT protocol, on the other hand, focuses on getting consistent results, whether qualitative or quantitative. A QIBA Profile includes clear specifications that cannot be altered by the user. In the UPICT protocol, because there are often legitimate reasons to alter image acquisition protocols, it is acceptable to edit acquisition parameters, for example in a phase 1 pharmaceutical clinical trial in a few sites trial, as opposed to phase 3 trials in multiple countries. So the standards will be looser in a large phase 3 trial.

Does the standardisation work have impl ications for costs and management in imaging centres, for example when conducting cl inical trials?

It will be important in reducing costs. When the standard is not tight, there is more variety in data collection, more “noise” in the data. So with standardisation we will see a shift from larger studies to smaller trials.

Wi ll this standardisation assist in reconci ling the requirements of imaging in clinical trials and imaging in clinical practice?

This is the goal. Some contract research organisations in the United States are promoting use ent.org of QIBA Profiles to their clients. For example , the market leader in transmitting scans from sites to laboratories has developed software that automatically determines if scans meet the QIBA Profile criteria or not .

Is it fair to ask why the development of quantitative imaging biomarkers has taken so long? What are the potential obstacles?

It is fair to say that the development of biomarkers has taken a long time. They all (both imaging and specimen biomarkers) face the same hurdles. There is a lot of anguish about this. For imaging there are even more acute problems in development .

The factors af fecting development are: firstly, the science is difficult . Secondly, the business case is weak. There are so many alternatives that it is hard to know what the best payoff will be. It’s a gamble.

It is a challenge to get a single protein or the imaging phenotype to uniquely reflect a complex disease. Obtaining dat a from clinical trials to prove that is difficult and expensive, and clinical trials take a long time.

The cost of doing scans is much higher than a laborator y specimen test . This is an impediment for companies to invest in imaging biomarkers in clinical trials. There has been relatively little commercial sector investment in research in biomarkers. The business case is unfavourable. The cost to develop a PET scan agent , for example, could be several hundred million dollars . The revenue st ream is not there to justify that investment in many cases.

Technological improvement is a hindrance also. Technology gets obsolete very quickly. There is not the same benefit from patent protection as there is for a drug. Technology turns over in just 2-3 years.

At the 2013 QIBA working meet ing delegates were asked: how do we estimate the value of quantitative imaging before it is implemented and measure i ts value after implementation? What was the progress?

This is not core work for QIBA. However, it is impor tant that the imaging industry be interested in looking at the value to them, co-payers and clinicians. The biggest impediment is the clinical utility issue. Relatively few treatment decisions currently are driven by quantitative imaging results. It’s a chicken and egg situation. You cannot ef fectively evaluate the cl inical utility of an imaging biomarker, because the numbers are not reproducible. QIBA’s work is foundational, establishing the threshold for quantitative imaging. For example, in heart disease, with several different treatments now available for congestive heart failure, if physicians could accurately measure a small change in ejection fraction it might trigger a change in therapy. For that to happen you might have to provide the ejection fraction at 5% precision. For chronic obstructive pulmonary disease, you might have to be able to measure a 1% change sufficient for pulmonologists to make a change in therapy. In Alzheimer’s a very small (3-5%) change in the volume of the amygdala or hippocampus region might trigger a change in therapy. We don’t have the ability to make those precise measurements at the moment, however.

Given current controversies in the U.S. regarding reimbursement for CT screening for lung cancer, will quantitative imaging assist in gaining more support for this?

Leaving aside the issue that Centers for Medicare & Medicaid Services (CMS) decision-making is influenced by political issues as well as scientific ones, QIBA is developing a Profile for CT screening for lung cancer. Marshalling and gathering the evidence for using objective volumetric measurements will, we believe, address the CMS concerns about the lack of consistency and should also reduce false positives.

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