

## QIBA Contrast Enhanced Ultrasound (CEUS) Biomarker Committee (BC) Call

Friday, September 13, 2019; 11 AM CT

### Call Summary

#### In attendance

Mike Averkiou, PhD (Co-Chair)

Todd Erpelding, PhD (Co-Chair)

Sherwin Chan, MD, PhD

Christian Greis, PhD

Ged Harrison, BS

Luna Hilaire, PhD

Reinhard Kubale, MD

Zaiyang Long, PhD

Nancy Obuchowski, PhD

Shigeto Ono

Lihong Pan, PhD

Thierry Rognard

Theresa Tuthill, PhD

Stephanie Wilson, MD

#### RSNA

Joe Koudelik

Julie Lisiecki

**Moderator:** Dr. Averkiou

#### Approval of 05.10.2019 call summary

- The summary was approved as presented

#### Bubble Conference Update

- The Bubble Conference was in Chicago September 5-6, and much new research was highlighted at this meeting
- Dr. Averkiou noted that the FDA participated in this meeting and he was very happy for their involvement
  - He hopes that a QIBA representative can be present at future Bubble Conferences to encourage new partnerships and collaborative research efforts

#### US Q3 Coordinating Committee Update, 8/23

- Dr. Averkiou noted that the BC will now focus on Profile creation and asked for subject-matter-expert volunteers to draft sections
- Dr. Averkiou will begin a rough draft of the Profile but requires input from BC members
  - He is currently working on an in vitro study manuscript, which may be helpful in providing some background detail for the Profile
- Dr. Erpelding was requested to oversee the industry portion of the Profile

#### QIBA US Modality Poster for RSNA 2019

- The focus of the posters this year has been changed in hopes of appealing to the broader radiological community and demonstrating how QIBA and QI are valuable, and can enhance clinical practice and clinical trials
- Each modality will have one poster, which will be a combined effort across their respective BCs
- The posters should be visually appealing, with more images and less text
- Emphasis should be on the impact of QI and showcasing (marketing) the work and benefits of QIBA
- Suggested topics to include in the poster were discussed:
  - Data re: radiological contrast use potential
  - Data from companies, such as Bracco, Canon, GE, Lantheus, Philips, Siemens, etc., demonstrating quantification use in CEUS on scanners
  - Percent of echocardiography exams that are performed with quantification and contrast (Dr. Wilson)
  - Uptake of contrast used in the abdomen might be helpful, though not all of the data are available for domestic usage
- Bracco has the most widely used quantification software, which currently is not available in the US
  - Using a PubMed search was suggested to find data
  - Dr. Rognard to forward a list of papers published that utilized Bracco's quantification software

- Dr. Chan, pediatric radiologist, noted that echo data is not as relevant in the US
  - He will follow up with Dr. Averkiou regarding other more commonly used methods that might be highlighted
- It was also noted that Bracco's VueBox has not yet been approved by the FDA for use in the US
  - This is not at the top of Bracco's list, though it is desired by US and Canadian physicians
  - The software would have to be registered as a medical device, and there is significant paperwork needed
  - Dr. Wilson is endeavoring to get this request to the top of Bracco's list again
  - Bracco's software is available in Europe, South Korea, and is in the registration process in China
- The FDA's decision to approve a bubble for the treatment of children has made a huge difference in the US
- BC members expressed interest in submitting a formal abstract for a scientific poster for RSNA 2020
  - A draft abstract would need to be ready for submission prior to the April 2020 deadline
  - A larger scale poster might expand on the value of QI
- Dr. Averkiou noted the names of those who will be sending him information for the poster
  - He asked that all volunteers send information right away so as not to forget
- Dr. Carson has volunteered to coordinate and assemble the poster for all US BCs; content submissions should be submitted **no later than Oct 12<sup>th</sup>**

**Proposed Collaboration with the International Contrast Ultrasound Society ([ICUS](#))**

- Dr. Wilson suggested that QIBA collaborate with ICUS, and Dr. Averkiou proposed a joint request from QIBA and ICUS to the FDA re: VueBox software
  - Their primary goal is to obtain approval for use of the VueBox software in the US and Canada to encourage a favorable collaborative environment for quantification
- A recent white paper on contrast use as part of the application for FDA approval may prove helpful
  - Dr. McCarville was mentioned as a helpful resource regarding this paper

**Next steps:**

- The process of drafting the CEUS Profile will begin

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 The next scheduled QIBA ultrasound calls will be as follows at 11 am CT:

|              |                                   |
|--------------|-----------------------------------|
| <b>10/04</b> | SWS BC                            |
| <b>10/11</b> | CEUS BC                           |
| <b>11/08</b> | RSNA 2019 print-ready Posters due |
| <b>11/15</b> | Q4 US Coordinating Committee call |

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