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Published on *IVT Network* (http://www.ivtnetwork.com)

A Benefit-Risk Collaborative Community

By Roberta Goode Jan 23, 2019 6:14 am PST

In January 2018, FDA published its strategic priorities for 2018-2020.[1] Building on the success of public/private collaboration on projects such as Case for Quality, FDA announced its intent to increase collaboration with private industry with the following bold metric:

> "By December 31, 2020, establish at least 10 new Collaborative Communities."

The hallmark of a Collaborative Community is a continuing forum where public and private sector members proactively work together to solve problems salient to a particularly challenging practice or unmet need in the medical device industry. CDRH's commitment to participate in the Community alongside medical device manufacturers, patients, and other stakeholders demonstrates a tangible departure from the enforcement mentality of years gone by. As stated in FDA's Strategic Priorities report :

> "[Collaborative Communities] will enable our customers to take a more active role in the advancement of smart regulation and the rise of Patient Scientists— those scientists, health care professionals, engineers and others who focus on serving the unmet and developing needs of patients and who incorporate their own experiences as or with patients into their work in industry, health care, and government."

I approached FDA in early 2018 to recommend the first Collaborative Community on the topic of Benefit-Risk. Based on industry feedback gathered from her medical device manufacturing clients over the past 30 years, Goode identified gaps in industry and FDA interpretation and implementation of risk-assessment and benefit-assessment. Goode believed a CDRH-approved Benefit-Risk Collaborative Community (BRCC) could advance the medical device industry if it were to achieve the following goals:

- Share robust practices for assuring device benefit outweighs device risk across the total product lifecycle, from the design phases through postmarket activities,
- Inform FDA of the practical challenges of compliance with the associated standards and guidances in Benefit - Risk and Risk Management, with the goal of collaborating on more practical approaches, and
- Design a suite of quality tools and templates that could become industry standards and best practices for FDA and medical device manufacturers in the US and beyond.

CDRH agreed to the proposed Benefit-Risk Collaborative Community and provided two representatives, Mr. Francisco Vicenty (Program Manager - Case for Quality) and Dr. Adam Saltman (Clinical Director – Benefit/Risk) to participate in the inaugural meeting. The first meeting of the BRCC took place in San

Diego in October, 2018, at IVT's 24th Annual Validation Week event.

The BRCC meeting brought together industry leaders from across the medical device manufacturing landscape, along with FDA, to consider how to best serve patients and industry manufacturers by developing practical tools for the application of benefit and risk assessment to medical device quality decisions. Among the four areas of influence in benefit-risk assessment (benefit pre-market / risk pre-market / benefit post-market / risk post-market), the BRCC agreed to begin with benefit post-market and its feedback to the relevant elements of design control (user needs, design inputs, design verification, design validation). Proposed deliverables include white papers, pilot studies, new or revised guidance documents, templates and best practices for assessment of benefit and risk both pre- and post-market, a benefit-risk helpdesk, and an educational suite of products potentially including FAQs, myths, failure modes, webinars and case studies.

With FDA's Collaborative Communities Toolkit [2] , the BRCC accomplished the following objectives in October 2018:

- Established the BRCC vision,
- Defined membership guidelines,
- Discussed internal and external communications practices,
- Established a charter, including goals, shared outcomes, objectives, constraints, scope, governance, stakeholders, and timelines,
- Considered a suite of metrics to quantify our effectiveness going forward, and
- Agreed to meet quarterly hereafter to continue our progress.

BRCC Subcommittees were also designated, and will meet independently to determine the details in several key areas of our work, which will be shared with the larger group at our next general organizational meeting in March, 2019. That meeting, which is being hosted by IVT at their upcoming Medical Device Validation Week in Minneapolis, will find the BRCC continuing its efforts to provide a quantifiable benefits model and tools for benefit-risk assessment to the medical device industry and the patients we serve. Stay tuned to IVT publications for news of our first benefit-risk deliverables, arriving in 2019.

Works Cited

[1] "2018-2020 Strategic Priorities," US Food and Drug Administration, Center for Devices and Radiological Health, January 2018.

[2] "Collaborative Communities Toolkit," US Food and Drug Administration, Center for Devices and Radiological Health, September, 2018.

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