

## Session 2: 17:10 – 17:25

### Development of a competency assessment framework for clinical research professionals



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#### Short CV

**Barbara E. Bierer, M.D.**, a hematologist-oncologist, is Professor of Medicine at Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH).

Dr. Bierer co-founded and now leads the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center), a collaborative effort to improve standards for the planning and conduct of international clinical trials.

In this capacity, she works with regulators, pharmaceutical companies, CROs, academia and patients/patient advocates to harmonize policies and approaches for multisite, transnational trials.

She is a co-founder of COVID-19 Collaboration Platform and of the non-profit Vivli, a global clinical research data sharing platform.

She is also the Director of the Regulatory Foundations, Ethics, and Law program at the Harvard Catalyst, and Director of Regulatory Policy for SMART IRB.

She serves as Faculty in the Center for Bioethics, HMS, and Affiliate Faculty in the Petrie-Flom Center for Health Law at Harvard Law School.

From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research, BWH where she founded the Brigham Research Institute and the Brigham Innovation Hub.

She is a past chair of SACHRP and has served or serves on the Board of Directors of AAHRPP, PRIMR, MSH, Vivli, North Star IRB, and the Edward P. Evans Foundation.

She has authored over 250 publications.

#### Abstract

##### **Development of a competency assessment framework for clinical research professionals**

The performance of high-quality clinical research requires an array of defined professional competencies for which training, education, and practical experience are necessary. Over the last decade, a diverse group of international stakeholders have worked together to harmonize the core clinical research competencies into a single, high-level set of standards that could be adopted globally and serve as a framework for defining professional competencies. First released in 2014, Joint Task Force for Clinical Trial Competency Framework has been periodically updated to include Fundamental, Skilled and Advanced levels, and more recently, competencies related to clinical project management. Additionally, the Framework has been used to align job descriptions and training modules, and case studies have highlighted real-world applications. The Framework has been translated into Japanese and Spanish; additional translations are in preparation. Two global self-assessment surveys demonstrate the utility in the approach, illuminating opportunities for further training.