State of the Science Research Summit

Working Group 6: Infrastructure
Welcome!

• Co-Chair
  • Children’s Hospital Los Angeles, University of Southern California
The working group

• **Stacy Croteau**, MD, Director, Hemophilia Treatment Center of Boston, Assistant Professor of Pediatrics, Harvard Medical School

• **Randy Curtis**, MBA, Patient Representative

• **Emily Krava**, MPH, CPH, CCRP, Clinical Research Coordinator, Children’s Hospital Los Angeles

• **Moses Miles**, Chief Operating Officer, American Thrombosis and Hemostasis Network

• **Lisa Pitler**, JD, MS, RN, CHRC, Healthcare Compliance Professional, Healthcare Regulatory Attorney, Research & Research Administration
Study site infrastructure

• Consists of people, processes and tools required to execute a research project at study site

• Two types of processes and tools:
  • Those that are unique to the study site or their larger institution
  • Those that have the potential to be either standardized or centralized between study sites

• The capacity of a study site often determines the ability of the site to participate in a study
So, how does this apply to research in general?
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- Basic translational research
- Investigator-initiated clinical studies
- Sponsored clinical trials
- Registries/ATHN studies
- Local retrospective studies

Site resource requirements
The teams

- Sponsor
- CRO
- Central Lab
- Pharmacy
- Clinical Research Unit
- IRB
- Contract team

Study Site
The players

- Investigators
- Data Manager
- Local lab
- Pharmacist
- Research Nurse
- Clinical Research Coordinator
- IRB coordinator
- Subject
The interfaces/websites (the short list)

- Sponsor site (protocols/investigator brochures, etc.)
- IWRS
- SUSARS/AE reporting
- Central lab reporting
- eCRFs
- Local IRB
- Central IRB
- Trial management software
- Electronic health record

Study team
So, how does this apply to research in the HTC?
Hemophilia center types

Federally-supported Academic Centers (University-based adult and pediatric hospitals)

Federally-supported Non-university Adult and Children's Hospitals

HTC and ATHN affiliates

Federally-supported Non-hospital affiliated private HTCs

Non Federally-supported centers
Research resources vary

[Sources of funding can include grants (HRSA/340B, CDC, other Federal grants, other grants), sponsored studies (pharma), philanthropy]

- Centers with significant resources for research
  - Many staff (CRCs, CRNs, IRB coordinator, research lab, etc.)
  - Can participate in most if not the full pyramid

- Centers with some funding for research
  - Some staff sufficient for some of the pyramid

- Centers with 1-2 staff members who perform double duty e.g. clinical nurses who function as research nurses
  - Generally, only participate in ATHN/CDC studies

- No dedicated research staff
  - May participate in some research (ATHN/CDC) volunteering their time
What should be the expectations?

- Not all centers can do all research
- Goal should be for **every** HTC to at least be able to participate in CDC Community Counts/ATHN dataset/ATHN Transcends
  - Funding and other support is required to achieve this
Dr. Ragni’s group will discuss funding sources

NHF/ATHN should work with the centers to achieve some semblance of equity. For example:

- More funds allocated to smaller centers in order to get everyone to the second layer of the pyramid
- Assistance with “start up” for centers that are not achieving the second level
- Development of a “centralized” research hub for services aimed at increasing the capacity of center to participate in research
- Provision of educational opportunities/training