# 3D 2018 DARTMOUTH DEVICE DEVELOPMENT SYMPOSIUM

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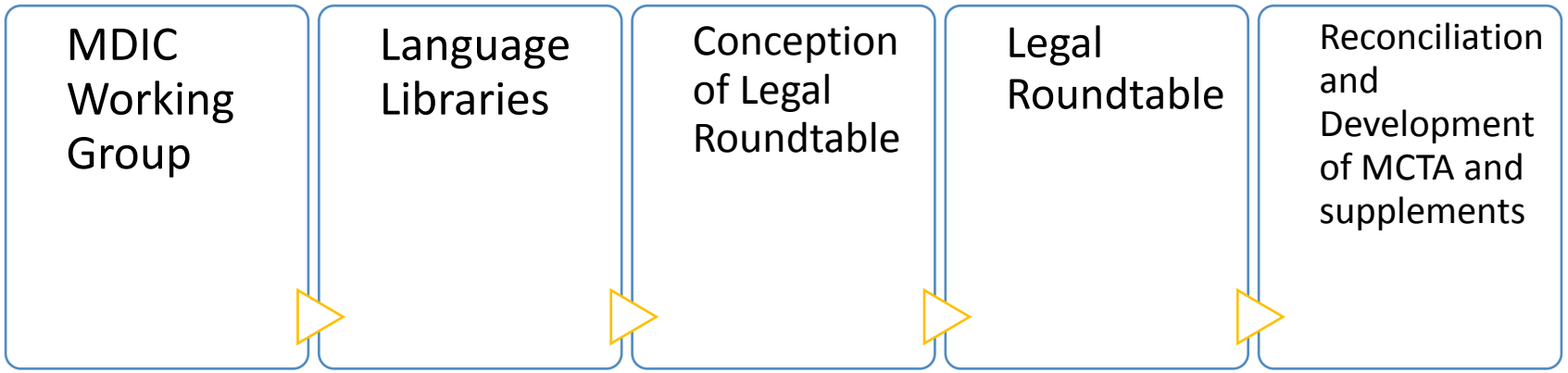
# Early Feasibility Studies (EFS)

## Value of EFS to a Site

- **Patients:** Patients' access to novel medical technologies
- **Research Program:** Earlier access to new medical device – supports research program growth
- **Pivotal Trials:** Familiarizes clinical sites with device/procedure before pivotal trials
- **Sponsor Relationship:** Strengthens relationship between the site and industry-sponsors

# Legal Roundtable



# EFS – Contracting

## 1. MDIC Working Group

MDIC approached four attorneys representing sites and sponsors to discuss some frequent key choke points in EFS contract negotiations:

- Indemnification
- Subject Injury
- Intellectual Property
- Third Party Payer

# EFS – Contracting

## 2. Language Libraries

- Each Library offers examples of clause language which has been acceptable to both sponsor and sites in the conduct of actual EFS trials, supplemented by respective Commentaries section.
- These commentaries describe important considerations and negotiation points, direct from some of the subject matter experts who engage in EFS contract negotiations.
- Intended to serve as a tool for sites and sponsors.

# EFS – Contracting

## 3. Conception of Legal Roundtable

- Develop an EFS-specific Master Clinical Trial Agreement (MCTA) to facilitate efficiencies in the EFS contracting process which provides:
  - balance between site and sponsor concerns, serving as a starting point for contract negotiations with a priori agreement of 90% or greater, and
  - allowing both parties to focus remaining legal resources on the remaining 10% (or less) of the EFS MCTA requiring negotiation

- Hosted by Baylor Scott & White Research Institute on February 8-9, 2018

# EFS – Contracting

## 3. Conception of Legal Roundtable

- BSWRI took the lead on drafting a MCTA template using the provisions from the Language Library developed by MDIC Working Group
- Draft MCTA circulated for review to the Legal Roundtable participants prior to the meeting

# EFS – Legal Roundtable Representatives

Baylor Scott & White RESEARCH INSTITUTE

## SITES

- Baylor Scott & White Health
- Cedars Sinai
- Dartmouth Hitchcock
- Emory
- Columbia
- Intermountain Healthcare
- Lankenau/ Main Line
- Mayo Clinic
- Houston Methodist
- Northwestern
- Piedmont

## SPONSORS

- Abbott
- Boston Scientific
- Edwards Lifesciences
- Medtronic
- Mitralign
- Abiomed

## FDA

## MDIC

## 4. Legal Roundtable

**Day 1**

- Four attorneys from the MDIC Working Group facilitated contract language discussions on the four choke points
- Edits made in real time in alignment with feedback received from the participants
- Interactive and productive discussions
- Revision to select sections was rather challenging due to differing viewpoints on these key items:
  - Intellectual Property
  - Indemnity

## 4. Legal Roundtable

**Day 2**

- Review of the MCTA language
- Addressing additional sections not identified as key choke points
- Revised template sent to the group at the conclusion of the meeting to review the remaining terms of the agreement

# EFS – Contracting

## 5. Reconciliation and Development of MCTA and Industry- and Sponsor-specific supplements

- Second review of the MCTA draft resulted in better understanding of organization's variances from the template and led roundtable participants to the conclusion that MCTA alone would not resolve all concerns and that supplemental information would be necessary
- Written summaries of variances along with narrative explanation serve as a supplement to the MCTA that equips people to efficiently make decisions on which institutions and sponsors to approach – reduces timeline to establish - eliminates meaningless negotiations

# Conclusion

- Overwhelming response from the participants implies shared enthusiasm to continue the Legal Roundtable to further improve the MCTA template
- Monitoring of contracting turn-around time by MDIC

# Conclusion

- Regulatory efficiencies
  - Standardized consent form
  - Value to explore willingness of sites to consider Central IRBs, collective recognition of good central IRBs and requirements
- Operational best practices
  - Budget
  - Coordinator training
  - Finding right patients
  - Standardizing patient care and experience across sites