

Clinical Trial Contracting at UC

Achievements and Goals

UC BRAID Retreat
October 15, 2013
Hillary Noll Kalay

Agenda

- **Achievements**
 - Master Agreements
 - Increased training and resources
 - Clarified policies and processes

Agenda

- Achievements → Goals
 - More Master Agreements
 - More training and resources
 - Additional Clarified policies and processes

Agreements: Achievements

- Abbott Vascular
- AbbVie
- Allergan
- Alvine
- Astellas
- Bayer
- Cook
- Gilead
- GSK
- Lilly
- Merck
- Pharmacyclics

Agreements: Goals

- Boehringer Ingelheim
- Biogen Idec
- EMD Serono
- Gore
- Janssen
- Otsuka
- Seattle Genetics

- Investor-initiated master agreements

- And more...

Training and Resources

- Achievements
 - Sharepoint site now a vital resource for negotiators
 - One-day in-person intensive training session
 - Annual in-person meeting
 - Intellectual property, health records, PPSA
 - Model device and PI-initiated CTAs

Training and Resources

- **Achievements**
 - Sharepoint site now a vital resource for negotiators
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 - Annual in-person meeting
 - Intellectual property, health records, PPSA
 - Model device and PI-initiated CTAs
- **Goals**
 - Additional and new training sessions
 - Rationale library

Clarified Policies and Processes

- **Achievements**
 - Exceptions to IP policies for Clinical Trials
 - New guidance
 - Subject injury policy
 - Intellectual property
 - PPSA

Clarified Policies and Processes

- **Achievements**
 - Exceptions to IP policies for Clinical Trials
 - New guidance
 - Subject injury policy
 - Intellectual property
 - PPSA
- **Goals**
 - Research restrictions
 - Data management
 - FCPA

Questions?

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