QA Working Group REPORT to GA Chicago June 2017

Bryce/Brand/Farrelly

Good Clinical Practice
Sarah Temkin, MD

- GCP and ICH
- GCP training requirements NIH
- Resources:

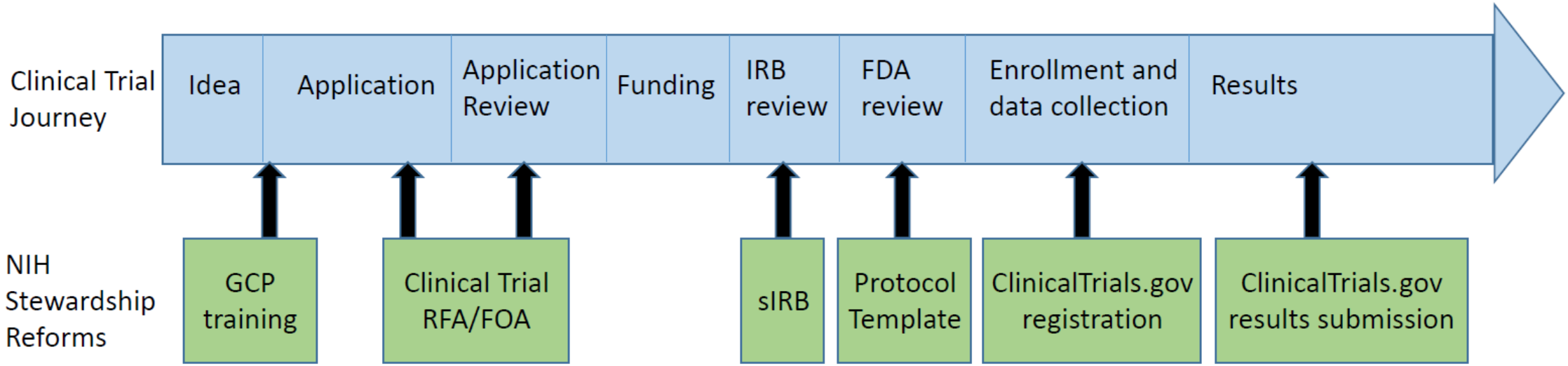
  CITI: citi.psu.edu
  NIAID: http://gcplearningcenter.niaid.nih.gov/
  Clinical Trial Network: https://gcp.nihtraining.com/

  GCP Training taken through CITI will be automatically recorded in CATS IRB. Completion reports from any other GCP training should be sent to IRB-ORP@psu.edu.

  For questions related to this new NIH-imposed training requirement or about which GCP training is most appropriate for you, please contact your IRB Analyst or the IRB Program at IRB-ORP@psu.edu.

Improving Clinical Trials: "Toward a New Era of Trust and Transparency in Clinical Trials"

Kathy L. Hudson, PhD; Michael S. Lauer, MD; Francis S. Collins, MD, PhD



eFigure. Improving Clinical Trials. The new, multifaceted effort shown above will enhance the quality and efficiency of NIH-supported clinical trials by focusing on a variety of key points along the "lifespan" of a clinical trial.

JAMA (2016)

QA Working group ongoing projects:

- Consensus on min evidence of GCP compliance
- Vendor assessment
- Site qualification by groups
- Minimum elements in a trial QA plan
- Standards for assessing trial risk and centralized monitoring.

Gynecologic Cancer InterGroup draft v1

QUALITY ASSURANCE BRAINSTORMING

November 2, 2017, 8:00am – 2:00pm, XXXXXXXXXXXXX, Vienna

Chair: Jane Bryce Co-Chairs: Alison Brand and Laura Farrelly

PROGRAM

Please sign in on attendance sheets

8:00am	Welcome and Introductions
8:15am	A. Evidence of GCP Compliance (QA documentation Standards for GCIG)
8:45am	B. Standards for assessing risk and centralized monitoring (is trial QA plan)
9:15am	C. Vendor/partner assessment (includes site evaluation)
9:45am	Panel – Q's & A's --- general Discussion
10:15 am	Beverage Break
10:45am	BreakOut Groups A B C
12:30pm	Lunch
1:30pm	BreakOut Groups Reports
1:30pm	A. Report (10 min) & Discussion (20 min)
2:00pm	B. Report (10 min) & Discussion (20 min)
2:30pm	C. Report (10 min) & Discussion (20 min)
3:00pm	Conclusions & Future Directions

ADJOURN