Regulatory Education for Industry (REdI) and CERSI Workshop

Current State and Future Expectations of Translational Modeling Strategies to Support Drug Product Development, Manufacturing Changes and Controls

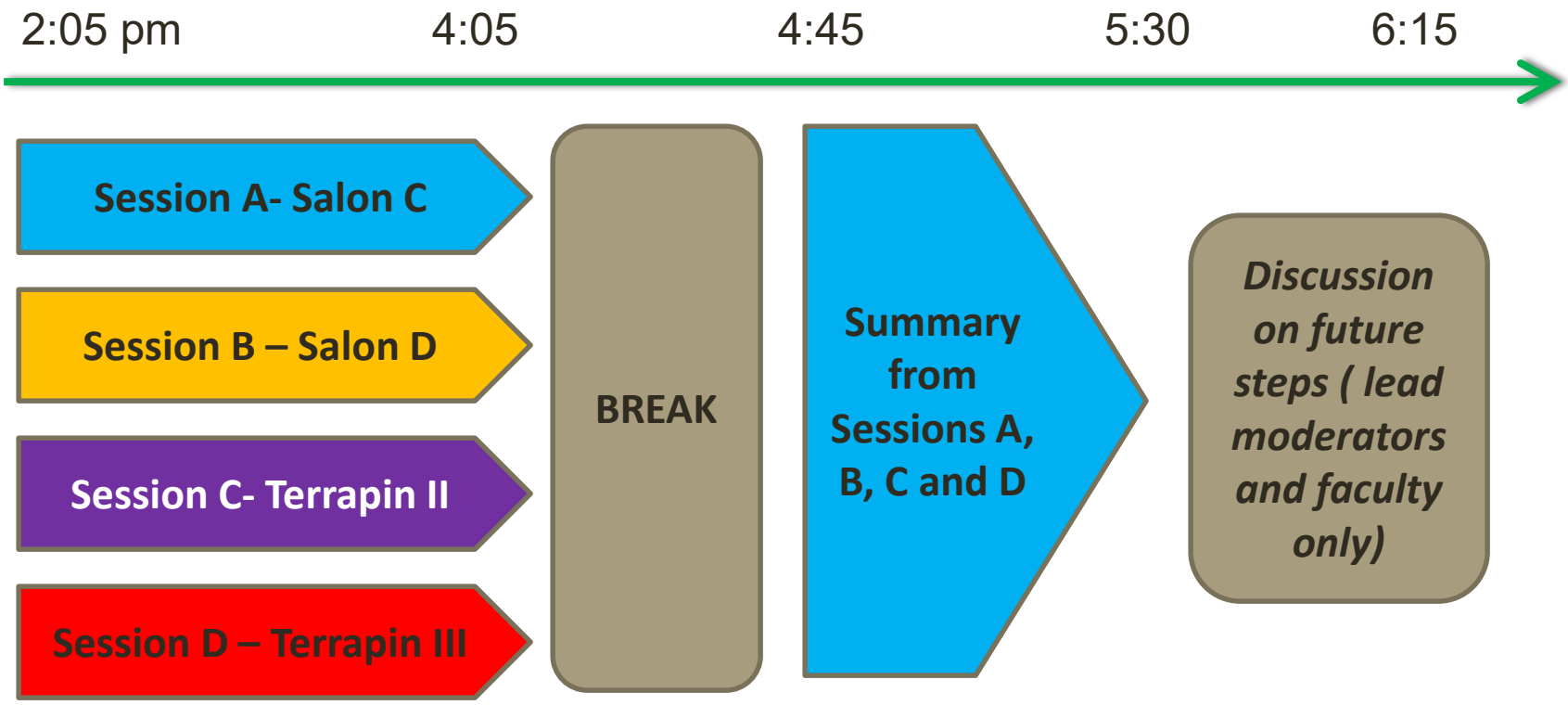
September 23-25, 2019

College Park, MD

DAY 3 BREAKOUT INTRODUCTION

Applications of PBBM to support Drug Product Quality

D3 BO Organization



- 2-hour BO sessions running in parallel
- Please respect your session assignment (you can see the colors on your badge)
- Series of questions for each BO topic for discussion (order of importance)

D3 Theme: Applications of PBBM to support Drug Product Quality

Breakout Session A - Salon C

Discussion of several terminologies related to physiologically based pharmacokinetic modeling in support of drug product quality (e.g., physiologically based biopharmaceutics modeling)

Breakout Session B - Salon D

Risk-based approach in the development and implementation of PBBM modeling to support drug product quality (e.g., clinically relevant specifications setting)

Breakout Session C - Terrapin II

The Road towards harmonization among regulatory agencies on evidentiary standards for PBBM

Breakout Session D - Terrapin III

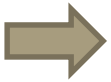
Strategies for bridging biorelevant and QC dissolution via PBBM

Day 3 BO: Expectations

- Short introduction by moderator: set the scene!
- Share knowledge and science: focus on addressing common challenges
- Discuss openly gaps in knowledge and how to address them
- Discuss examples of what works or not

- Be vocal, curious, share your opinion
- Propose ways forward: elaborate decision trees, propose to share data/experience, propose to form working groups, work on validation exercises

Publication planned following workshop : summarize current knowledge, discussions and proposals for future work



Clear succinct summary of each BO is essential

Day 3 BO: Expectations

Session A (*Terminology*):
Focus on CMC aspects (formulation & manufacturing)
Start with 2017 M-CERSI terminology table
Attempt to come-up with definitions that clearly defines the focus and scope of modeling in support of DP quality

Session B (*PBBM to support DP quality*):
Summarize the current state of PBBM in quality (e.g. CRS)
Discuss industry experience in regulatory submissions
What does the future hold?

Day 3 BO: Expectations

Session C (*Harmonization among Regulatory Agencies*):
Discuss & summarize challenges that industry & regulatory agencies face in the absence of harmonized requirements
Identify fundamental areas of opportunity for harmonization between regulatory agencies
No expectations to gain harmonization at this venue

Session D (*Bridging biorelevant and QC dissolution*):
Current industry practice for BCS 2/4 and MR products
Paths & challenges to bridge biorelevant and QC dissolution
Application of PBBM in bridging

Thanks!