

Agenda

During the evening prior to the meeting (September 25), those already in Berlin will gather in a restaurant close to the venue. If you are interested in joining, please contact

konstanze.scheurer@charite.de.

| TIME | MODULE | FORMAT AND TIMING | TOPIC | PERSON |
|---------------------------------------|--|---|--|-----------------------------|
| 09:45 – 10:30 Registration and coffee | | | | |
| Policies and portfolios | | | | |
| 5 mins | Welcome | Talk | Topics | Daniel Strech |
| 10 mins | Evolving requirements, structure of workshop | Presentation | WHO Joint Statement EU+US regulations Workshop overview | Till Bruckner |
| 35 mins | Strengthening and implementing institutional policies | 10 minute presentation + 15 small group exercises + 10 min roundup | Identifying gaps Communicating policies Roles & responsibilities | Tracy Petrie (Dundee) |
| 40 mins | Trial portfolio management: Legacy inventory and tracking ongoing trials | 15 minute presentation + 15 small group discussion + 10 min roundup | Making an inventory Assessing and updating trial status Tracking ongoing trials Tools and software solutions Resource requirements | Birgit Whitman (Birmingham) |
| 12:00 – 12:10: Coffee break | | | | |
| Managing EudraCT trials | | | | |
| 20 mins | Quick win: Uploading results of pre 2014 CTIMPs | 10 minute presentation + 10 QA | The pre-2014 rule Step by step guide Resource requirements | Birgit Whitman (Birmingham) |
| 15 mins | Quick win: Designing CTMIPs to make reporting fast and easy | 5 minute presentation + 10 QA | EudraCT reporting requirements Trial design process Data management | Tracy Petrie (Dundee) |

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| 60 mins | Posting results for post 2014 trials (retrospectively and ongoing) | 15 minute presentation + 5 QA + 30 small group exercises + 10 min roundup | Updating trial status Reporting older post 2014 trials Reporting newly completed trials Roles & responsibilities Resource requirements Challenges and how to overcome them | Jackie Pullen (Kings) |
| 13:45 – 14:30: Lunch break | | | | |
| Managing CT-gov trials | | | | |
| 45 mins | Managing trials listed on CT-gov | 10 minute presentation + 10 QA + 20 small group discussions + 5 min roundup | Setting up an institutional PRS account Getting rid of “ghost” trials Updating trial status Reporting trial results (incl differences to EudraCT) | Birgit Whitman (Birmingham) |
| 15:15 – 15:25: Coffee break | | | | |
| Making it happen | | | | |
| 50 mins | Roadmaps to excellence: where to start and what end to aim for (efficient systems covering all registries) | 20 minutes podium discussion + 20 small group exercises + 10 min roundup | Setting priorities Getting buy-in from management and PIs Overcoming challenges Roles & responsibilities Resource requirements | Tracy Petrie (Dundee) Birgit Whitman (Birmingham) Jackie Pullen (Kings) Angelika Kristek (Imperial) |
| 10 mins | Feedback from participants | | Lessons learned | Peter Grabitz |
| 5 mins | Closing remarks | Talk | | Daniel Strech |
| 16:30: Workshop ends | | | | |
| 19:00: Get-together for those still in Berlin (Location TBD) | | | | |

