

SA02

Going through an AdCom with the FDA – the Ultimate Programming Experience

Frederikke Høyer,
Project Programming Lead

Ferring Pharmaceuticals



Agenda

- What to expect from an Advisory Committee meeting
- How to prepare for the meeting as a Statistical Programmer
 - Subgroup Analysis
 - Process Tracking
 - Briefing Material
- My own experience from the AdCom Meeting

Advisory Committee Meeting (AdCom)

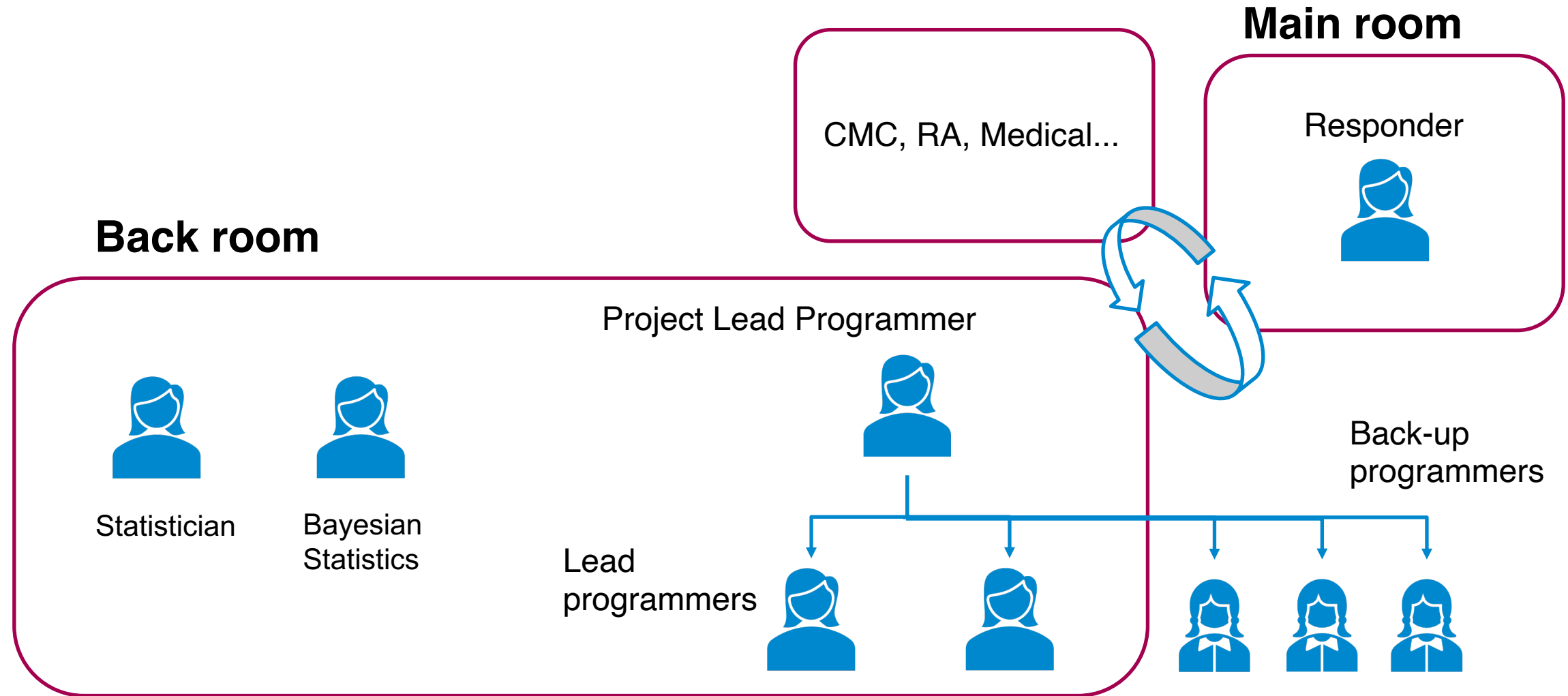
- Meeting to provide FDA with **independent advice** on scientific or technical matters from a panel of experts on products regulated by FDA
- The **panel members consists of scientific experts**, physicians, statisticians, engineers, chemists, biologists and other relevant professionals, consumer representative and industry representative
- Usually 9 fixed members including a chairperson with voting rights
- The advice from the panel is **not binding!**
- Not needed for all submissions – our case was a **first-in-class microbiota-based therapy**

<https://www.fda.gov/patients/about-office-patient-affairs/learn-about-fda-advisory-committees>

AdCom Meeting Agenda and Format

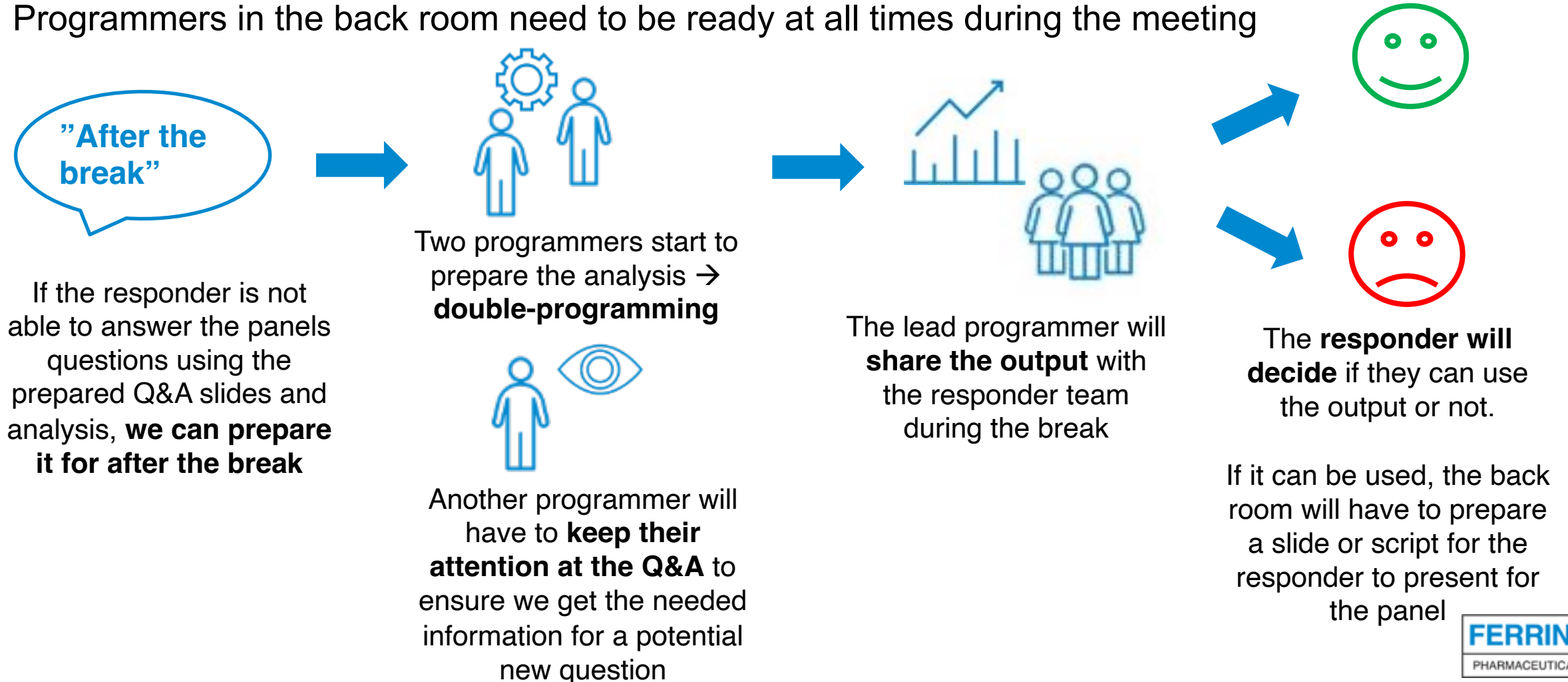
- Introduction of the panel
 - FDA presentation of the therapy and the voting questions
 - **Sponsor Core presentation** – including efficacy and safety – **following a Q&A session**
 - **FDA presentation of their own review of the submission** – **following a Q&A session**
 - Open Public Hearing
 - Committee debate and voting
-
- **Programming team in the "back room"**
 - Questions in the Q&A session can be answered immediately by the responder or **"After the break"**
→ Activates the back room!

Ferring AdCom Biometrics Team Structure



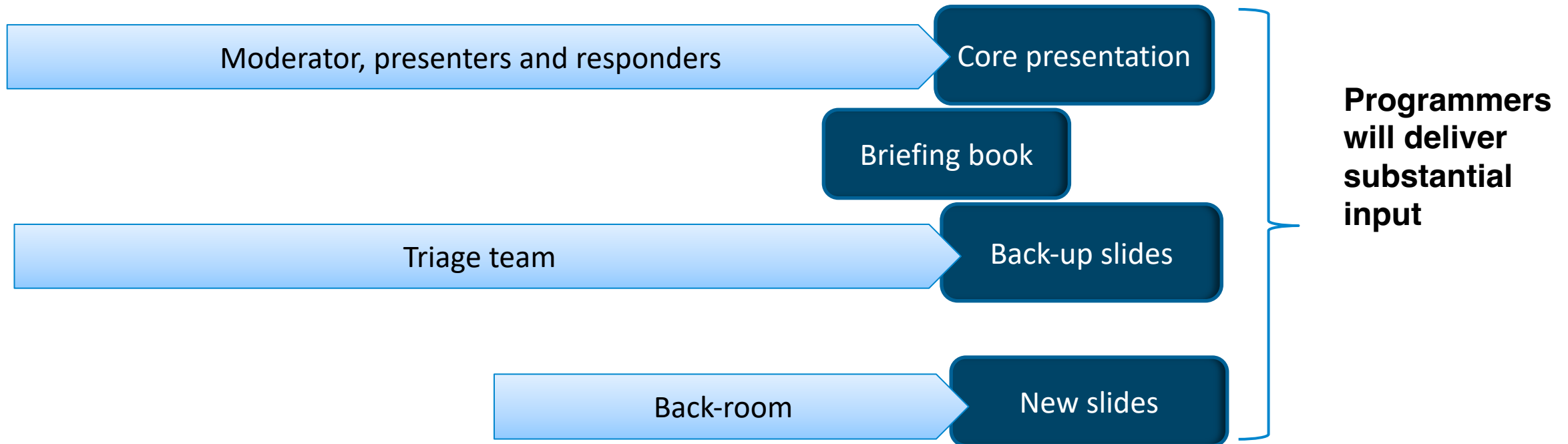
In the Back Room

- Programmers in the back room need to be ready at all times during the meeting



Preparation in Multiple Workstreams

Size of programming team depends on submission complexity and responsibility split between roles - minimum of three programmers – **but not too many!**



Subgroup Analysis

- Subgroup analysis are **essential for understanding the data** and to investigate patterns – chances the panel will ask for certain subgroup analysis are high
- Prepare your datasets and output programs for this
 - Create macros to handle subgroup analysis for all primary and secondary endpoints, all types of safety outputs and baseline measurements
- Search in literature and watch recordings from previous similar AdCom meetings for relevant subgroups and prepare the analysis

Summary of Adverse Events for Patients With Life-Threatening and Severe Events

Keep Track of the Analysis and Programming Status

- Keep track of more than 1000 outputs across multiple studies

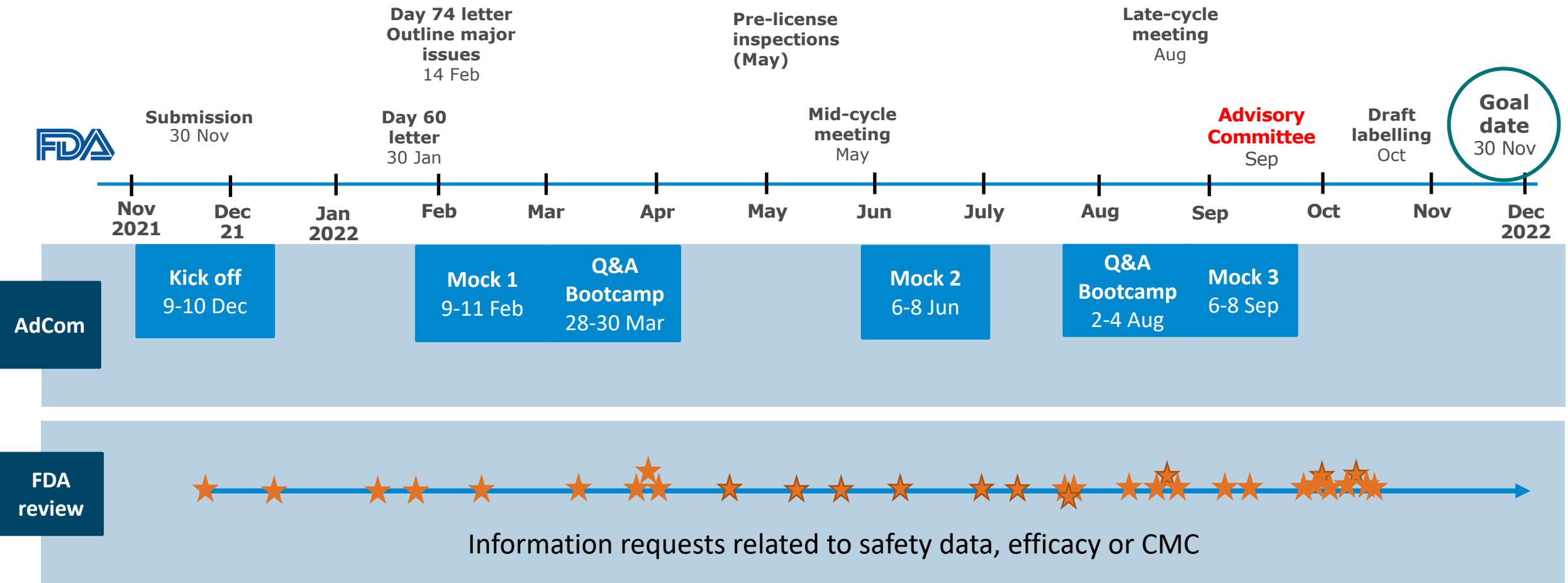
Study	Folder	Subfolder	Program	Details	Input	Output	Macro	Core	Back-up	BB	Status
2014-01	Stat	Safety	t_aesum14	Overall Summary of Treatment-Emergent Adverse Events Within 8-Week Follow-Up of Blinded Treatment or Censored at CDI Onset - Safety Analysis Set	adam.adae adam.adsl adam.adtte	t_aesum14_s	t_aesum_v1 tmpl_aesum_v1		SA-56	Table 10	Validated
2014-01	Stat	Safety	t_sae_soc14	Incidence of Treatment-Emergent Serious Adverse Events Within 8-Week Follow-Up of Blinded Treatment or Censored at CDI Onset by MedDRA System Organ Class and Preferred Term - Safety Analysis Set	adam.adae adam.adsl adam.adtte	t_sae_soc_ae_14y_s t_sae_soc_ae_14yol_s		CO-11		Table 11	Validated

- Internal processes might not be fit for the ad-hoc work in preparation for AdCom

*BB: Briefing Book

Timelines

Day 60 letter: Standard Review

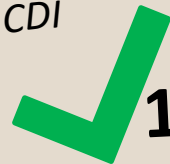


AdCom Meeting

Received overall positive votes at FDA AdCom with focus on the advantage of a regulated treatment

Efficacy

Are the available data adequate to support the effectiveness of the product to reduce the recurrence of Clostridioides difficile infection (CDI) in adults 18 years of age and older following antibiotic treatment for recurrent CDI

 **13**  **4**

Safety

Are the available data adequate to support the safety of the product when administered in adults 18 years of age and older following antibiotic treatment for recurrent CDI

 **12**  **3**
(1) abstain

AdCom Programmer Experience

- Be prepared and practice!
- A lot of work!
- Remember back-ups!
- Take the opportunity to become an equal partner with clinical team and other stakeholders
- **You will never know your data as good as after the AdCom**

Watch the Advisory Committee Meeting here:

[176th Meeting of the Vaccines and Related Biological Products Advisory Committee](#)