

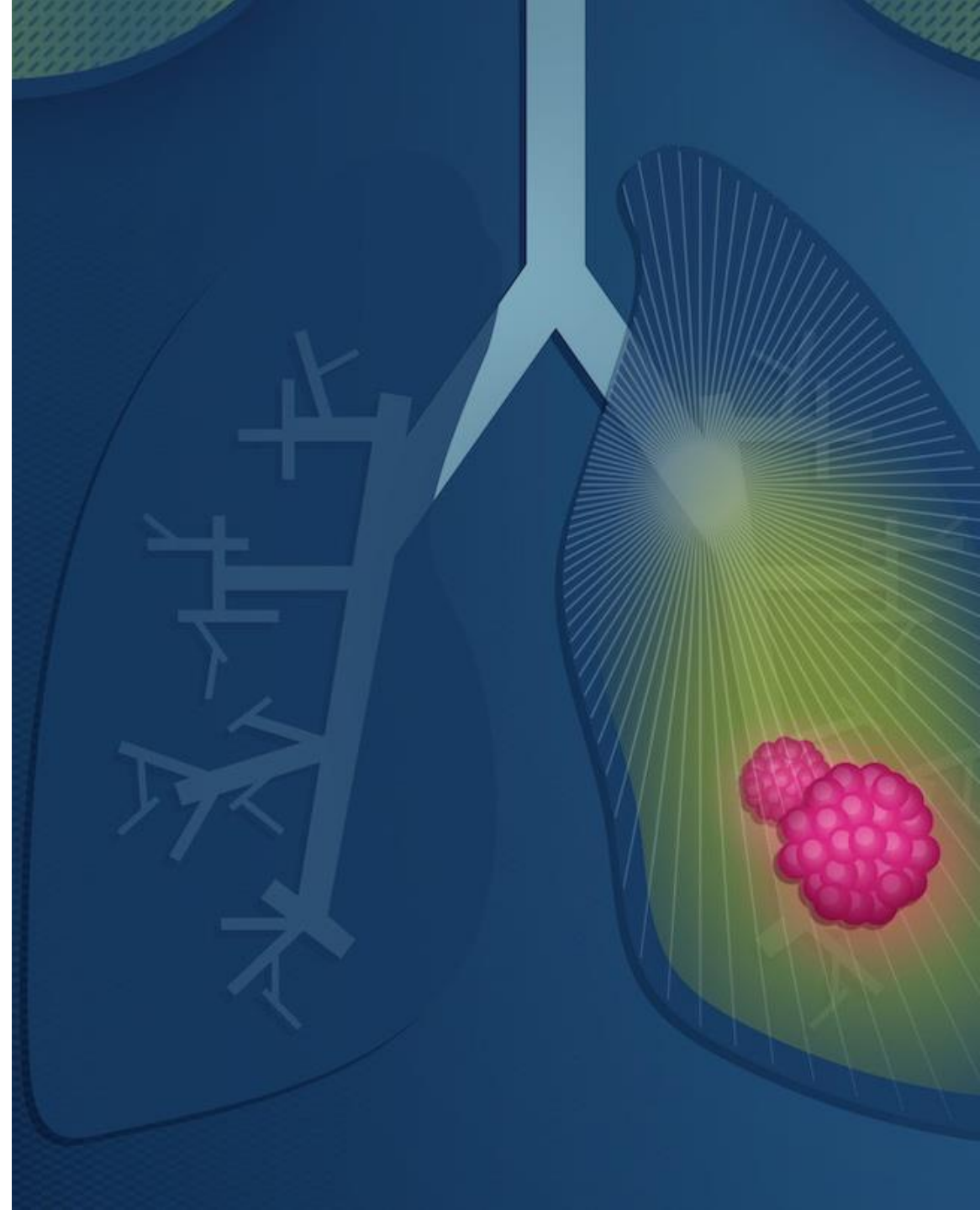


SA03: Oh Dear, Another Crisis? A Programmer's Guide to Surviving and Thriving Through the FDA ODAC

PHUSE EU Connect 2025

Zach Dorman

19th November 2025



What We'll Talk About



**Setting the
scene –
where we
were...**



**What is an
ODAC?**



**Planning
and
Preparation**



**Who is in an
ODAC
team?**



**The Final
Event..**



**Tips to
Survive and
Thrive...**



Disclaimer

This presentation reflects my personal views and interpretations and should not be taken to represent the official position, policy, or strategy of AstraZeneca.

All study-related facts cited in the presentation are sourced from the public domain (e.g., minutes from regulatory meetings, publications, and other public-facing sources).

For enquiries regarding ongoing trials, data clarifications, or official company commentary, please direct requests to the appropriate AstraZeneca Communications representative

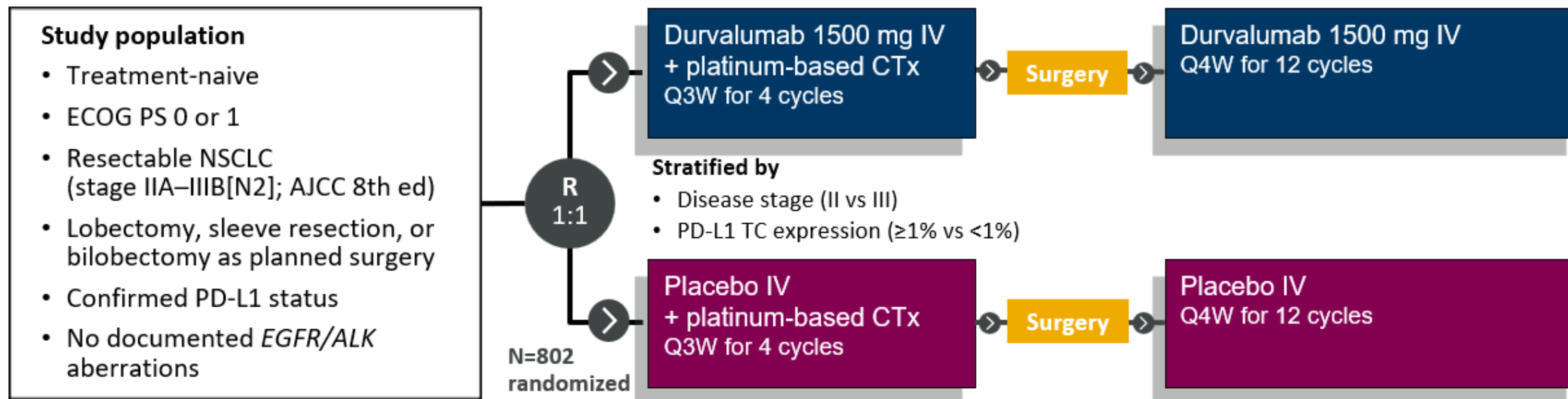


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Setting the scene – where
we were...



AEGEAN: Study Design



Endpoints	Primary	Key secondary	Other secondary includes
	• pCR (central lab) • EFS (BICR)	• MPR (central lab) • DFS (BICR) • OS	• Safety and tolerability • HRQoL/PRO • PD-L1 TC $\geq 1\%$: pCR, MPR, EFS, DFS, OS



Expected timeline from submission



ODAC announcement



2

What is an ODAC?



What is an ODAC?



ODAC = Oncologic Drug Advisory Committee

Provides independent expert advice to the FDA on broad scientific topics or on certain products to help the agency make sound decisions

Public hearing – streamed on



ODAC Agenda

Introduction
FDA Opening Remarks
Applicant Presentations
FDA Presentations
Clarifying Questions
Open Public Hearing
Questions to the Committee
(Discussion and Vote)



ODAC Questions – what was FDA concerned about?



Question 1: Discussion

sBLA 761069/S-043

IMFINZI (durvalumab) Injection

Applicant: AstraZeneca UK Limited

In light of the uncertainty around the need for both phases of treatment, discuss whether an additional trial should be conducted to clarify the contribution of treatment phase for the durvalumab perioperative regimen prior to approval.



Question 2: Vote

Future Perioperative Trial Designs to Support Contribution of Sequence

Should FDA require that new trial design proposals for perioperative regimens for resectable NSCLC include adequate within trial assessment of contribution of treatment phase?

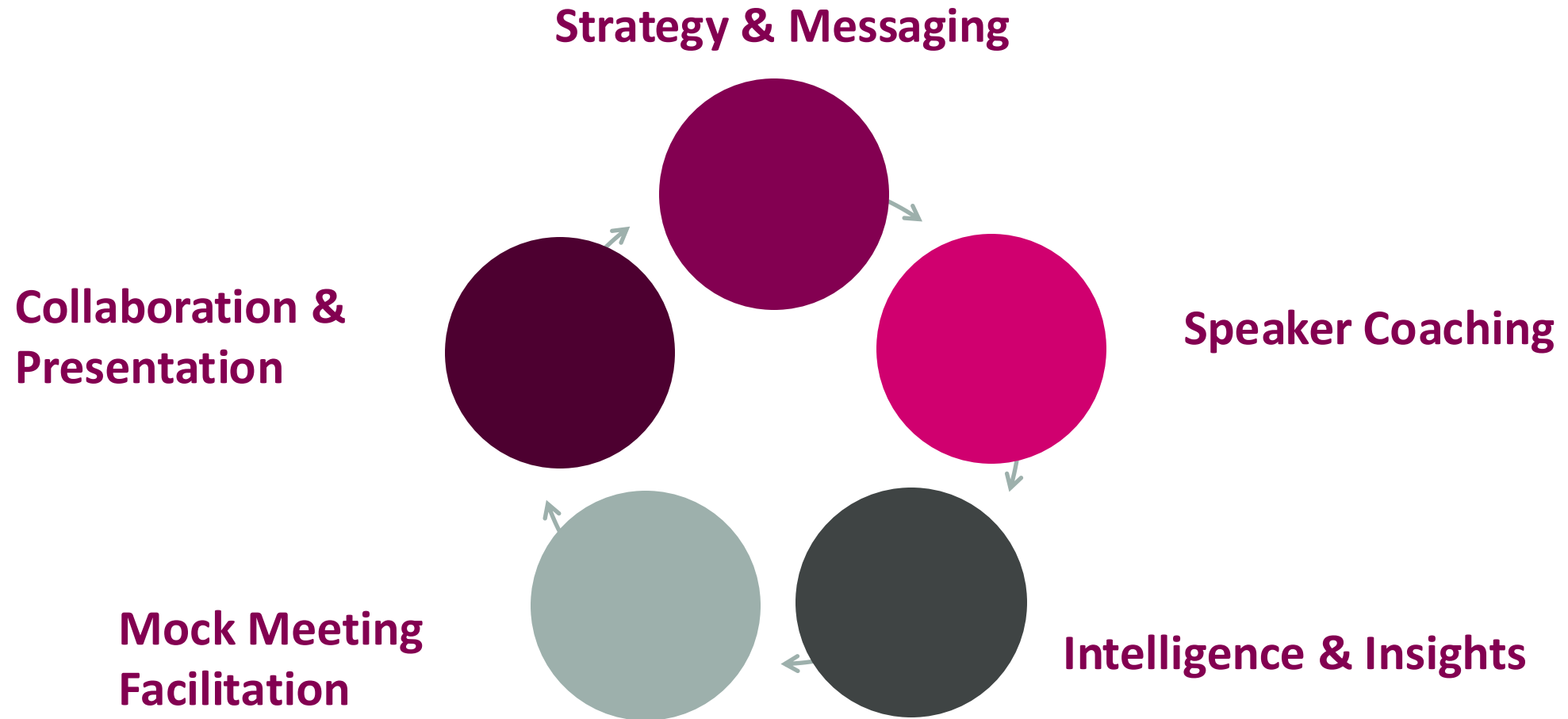


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Planning and Preparation



Planning – what support was required?



AZ's Objective and Presentation



Disease Background

Marina Garassino, MD
University of Chicago



Clinical Efficacy

Gary Doherty, MB, BChir, MA, PhD, FRCP
AstraZeneca



Clinical Safety

Mayur Patel, PharmD
AstraZeneca



Clinical Perspective

John Heymach, MD, PhD
MD Anderson



Closing Remarks & Future Perspectives

Leora Horn, MD, MSC, MHPE, FRCPC
AstraZeneca

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AEGEAN has a positive benefit-risk profile

2

AEGEAN helps address remaining unmet need for patients with resectable NSCLC

3

Considerations of designs for future perioperative studies to further improve patient outcomes

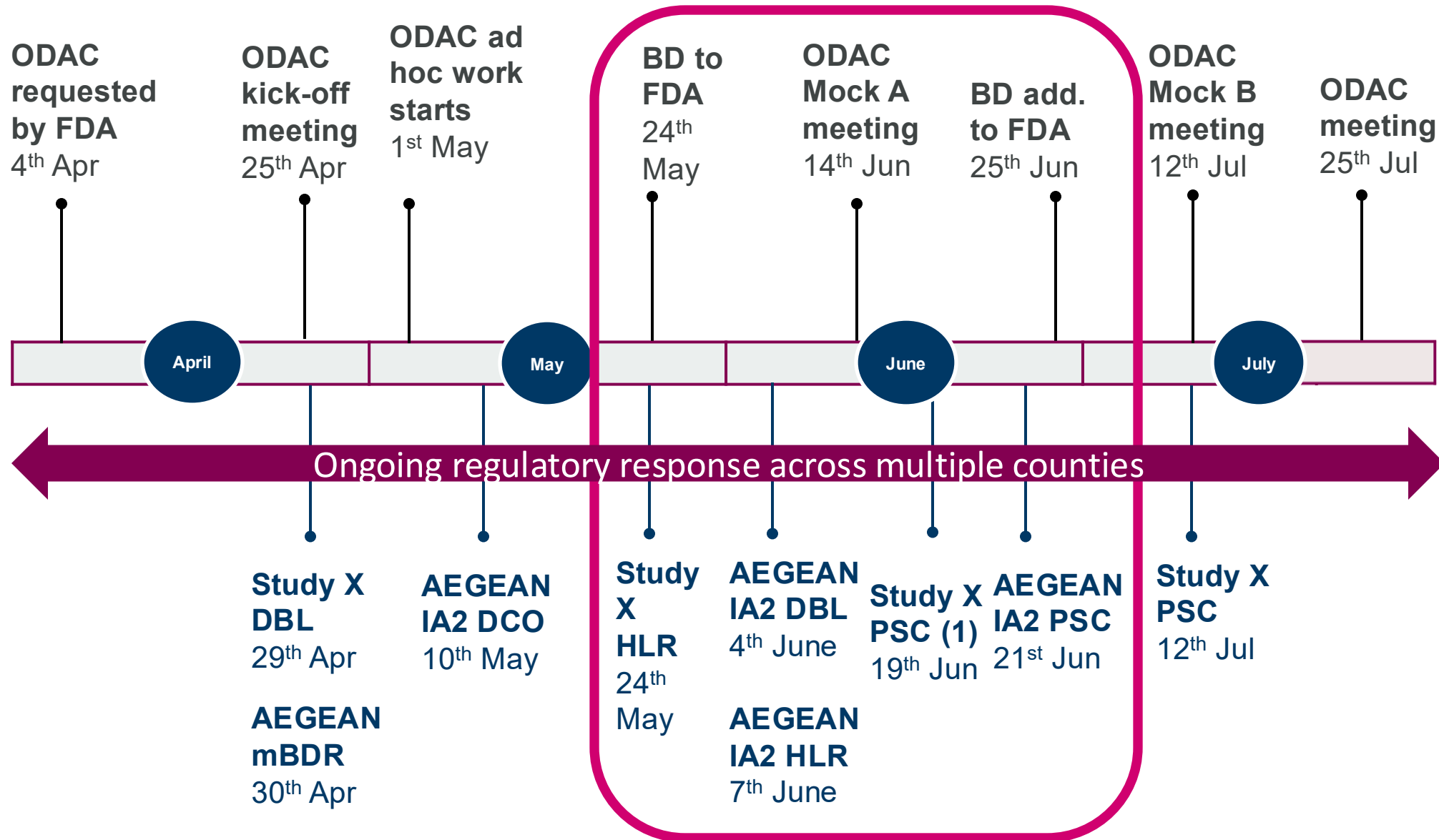


Where did Programming fit into this?

- Need to have slides prepared for all potential Q&A
- This required multiple ad hoc outputs to cover each of these
- Complexity – multiple studies and data cuts required in order to answer questions
- Needed to be planned in alongside other deliverables and timelines
- Programming team members sat on subteams answering the Q&A



Updated timeline...



ODAC Resource Planning

Number of Resources

ODAC
kick-off
meeting
25th Apr



ODAC ad hoc programming workflow

May

- Focus on ad hoc programming
- Ad hoc program tracker was setup to manage, triage and resource requests
- Consistent Prod/QC to build working relationships

June

- Team split in three to manage workload
- Internal stakeholder management for teams requesting ad hoc work
- Scheduled readouts across relevant triggered new ad hoc requests

July

- Leveraged vendor programming to support additional study-level requests
- Decrease in requests enabled programming team to work on other ODAC tasks
- Final total of 865 additional outputs produced to support ODAC meeting



[illegible]

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Who is in an ODAC team?



Programming roles and responsibilities

Global Product Programmer

Responsible for managing, triaging and resourcing ad hoc requests, and study oversight

Study Lead Programmer

Acted as technical point of contact for ad hoc programmers, as well as hands on programming of ad hoc requests

Back-up Study Lead Programmer

Led ongoing study activities, e.g. vendor QA, and helped programming of ODAC outputs when time allowed



Teams for the ODAC Meeting

Team in the Room



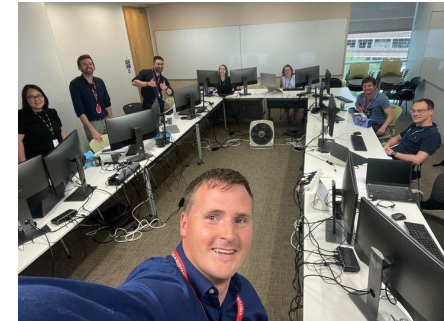
Text +
in
person

Behind the Scenes



Open
Direct
Line

Biometrics Room



- **Speakers** – Team who presents core presentation
- **Responders** - Team members to be called upon to answer questions
- **Slide callers** - Bring up slides for responders

- **Cross functional representatives'** key functions.
- Triaged requests as they came through from the ODAC
- Communicate response back to team in the room

- **Programmers and statisticians** – Study data Experts
- On hand to action any requests for which we did not already have a slide prepared



Behind the Scenes



Biometrics Team

**ODAC
Stats Lead**

**Stats Study
Lead**

**Remote-based
(USA)**

**2
programmers**

**Production
Statistician**

**Back-up
Statistician**

**QC
Statistician**

**Production
Programmer**

**QC
Programmer**

**ODAC
Programming
Lead & Room
Lead**



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The Final Event...



The Day of the ODAC

ODAC took place at the FDA headquarters on 25th July 2024

AZ presentation went well (as rehearsed!)

Q&A section focussed more on perioperative trial design, as opposed to specifics for our study

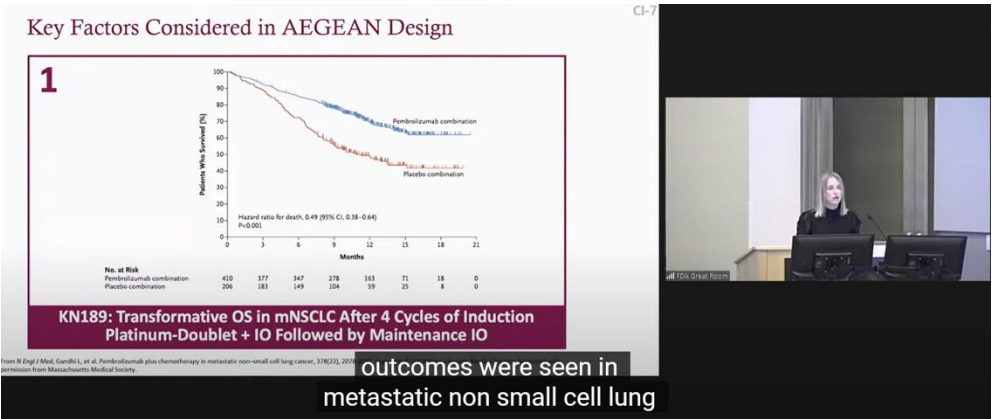
Discussion – deemed that the study was safe and effective, additional trial should not be a barrier to approval

Vote – Committee unanimously agreed that perioperative studies should account for contribution of phase for all future designs

The Biometrics team was not invoked during the course of the ODAC meeting itself

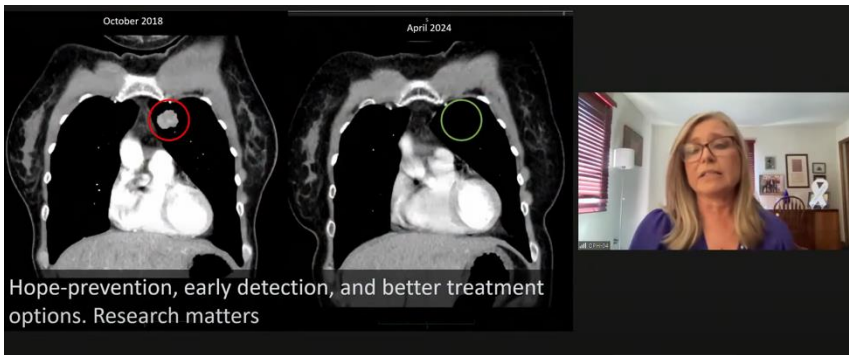


The Day of the ODAC



Yes	11	7/25/2024
No	0	1:32:18 PM
Abstain	0	
Non-Vote Member	0	

Yes	Vote: 11
Ashley Rosko, MD	Azam Ghafoor, MD
David Mitchell	Jim Pantelas
Ranjana Advani, MD	Ravi Madan, MD
No	Vote: 0
Abstain	Vote: 0
No-Voting	Total: 0



Time to relax after a busy day!



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Tips to Survive and Thrive...



What were the challenges?

Demanding workload

- Large amount of additional work to support potential questions
- Performed alongside scheduled study readouts – everything needed to be high quality

Stakeholder management

- Lots of different functions needed Programming input as part of prep for ODAC
- Had to manage competing priorities and personalities

External pressures

- FDA communications meant changing strategy for certain areas of presentation
- Led to different requests and rework for already-completed ad hoc work



How We Survived...

Team morale

- Daily check-ins for progress and mood
- Sharing the small wins – completion of ad hoc work to a key slide
- Programming team being part of wider team meetings

Understanding what was needed

- Clearly defined roles for a large stats and programming team
- Point people to liaise with key stakeholders
- Testing understanding before committing to programming

Communication

- Stats and programming regular check-ins
- Invites to strategy meetings
- Speak-up culture – able to contribute to discussions both within and outside of our function



How You Can Thrive...

Recognise it's challenging and novel!

- Large piece of work, under intense timelines – acknowledge this to your team regularly
- Have a clear plan prior to meeting on how to manage requests

Be adaptive!

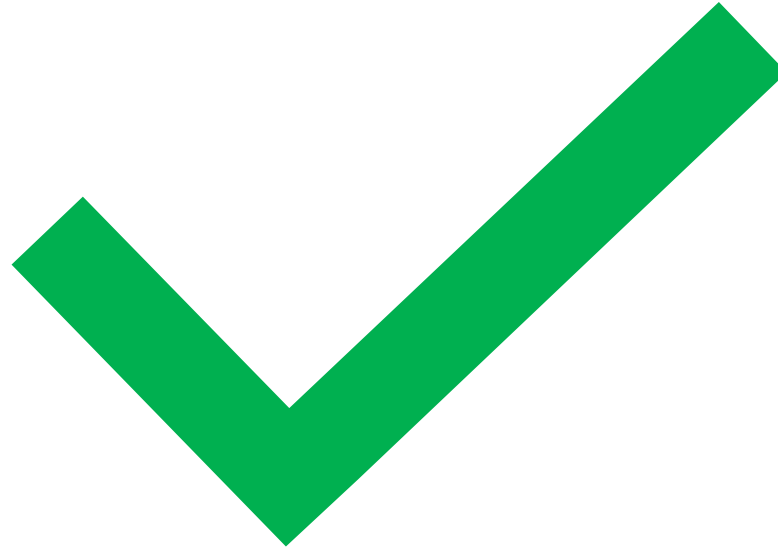
- Have an agile mindset – be prepared to move onto topics at short notice
- Don't take any rejection of ad hoc work personally – adapt to direction of travel for slide deck

Teamwork

- Try to play to people's strengths
- Get stakeholders onside early
- Ask questions and be involved in giving feedback to wider team



And finally...3 weeks post-ODAC...



APPROVAL!!



If you would like to discuss this further...

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Any Questions?

