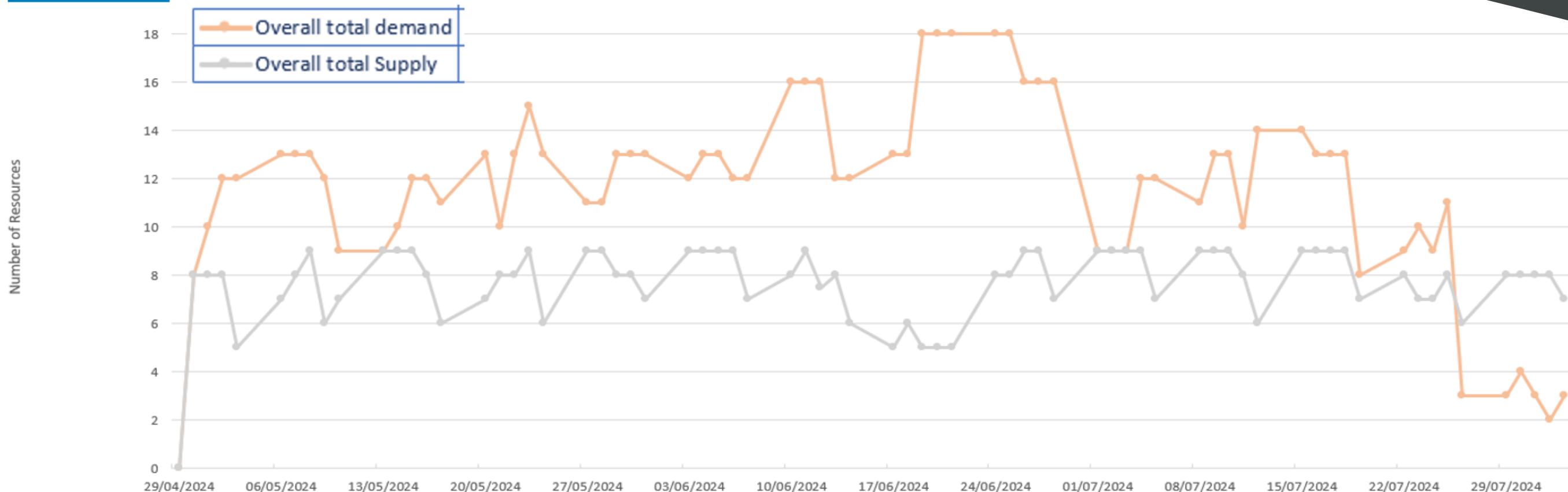
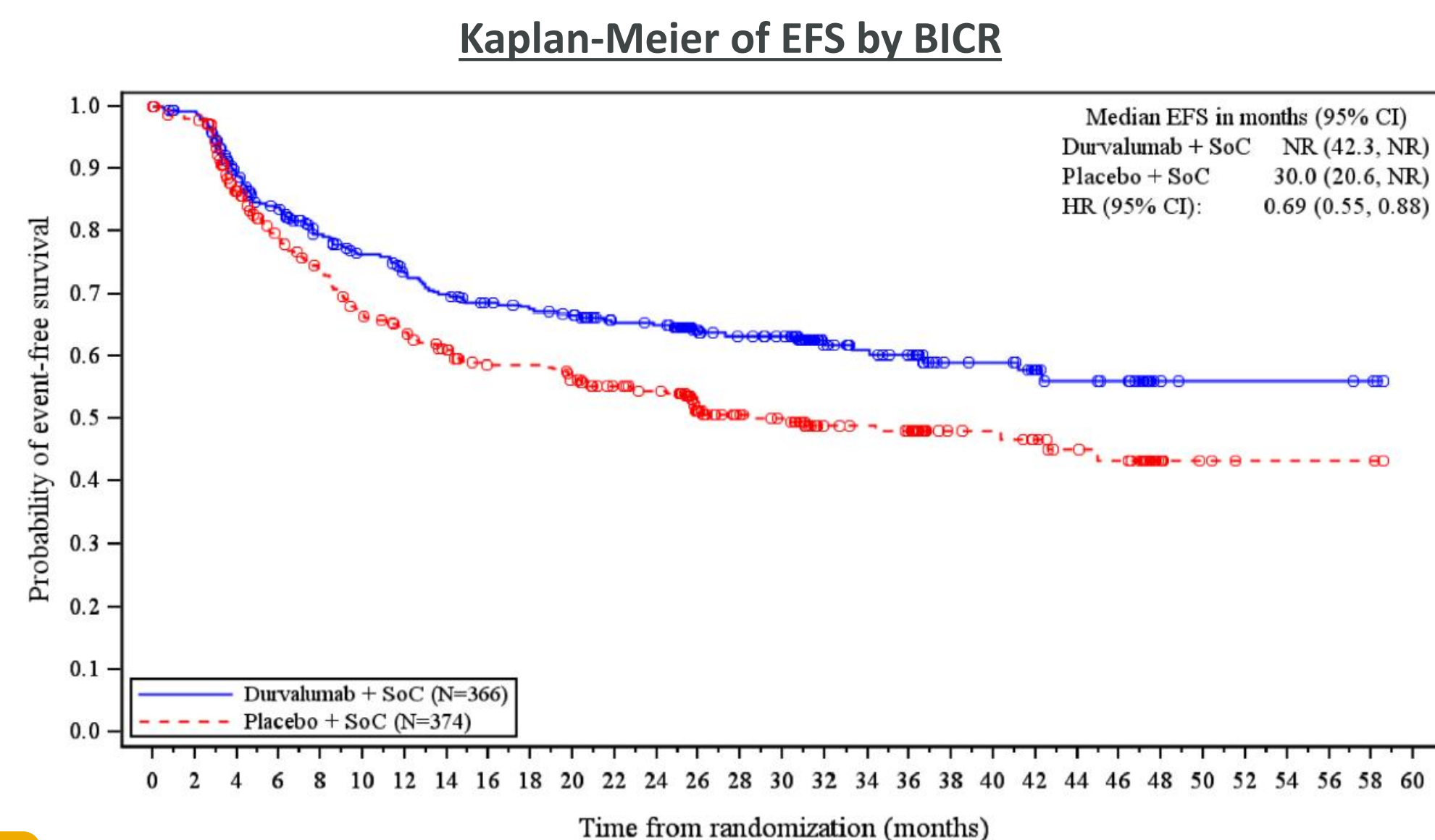
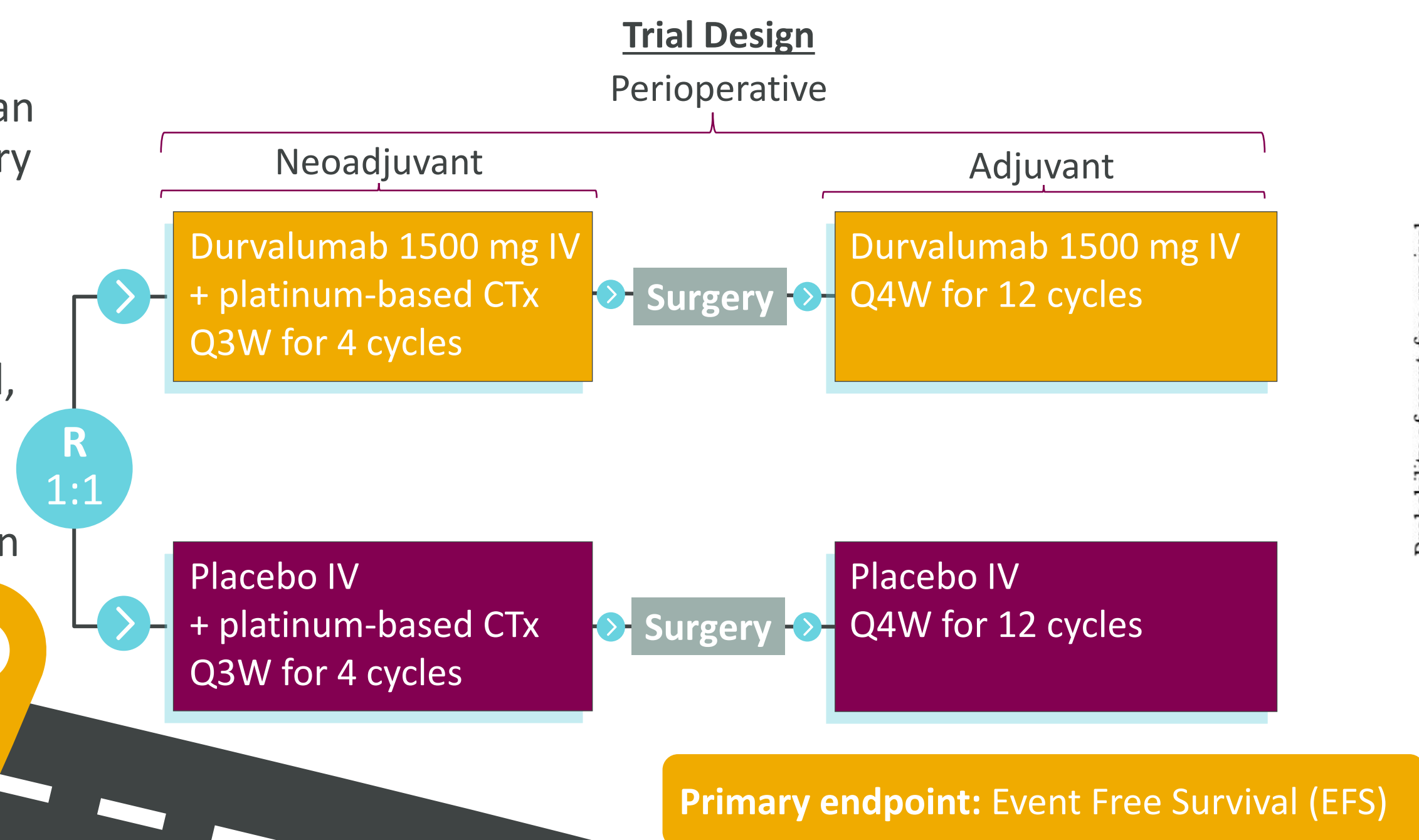


Charles Wright, Senior Programmer II

- In April 2024, the FDA informed us that they wanted to hold an ODAC in July of that year despite the study meeting its primary endpoints
- An ODAC refers to the Oncologic Drugs Advisory Committee which advises the FDA on the approval of cancer drugs
- Their concerns were with the perioperative design of the trial, and the contribution of treatment phases
- A formal vote was needed on future new perioperative trial designs for NSCLC, and if they should have an adequate within trial assessment of contribution of treatment phase
- Follow the road to go through the journey to the ODAC

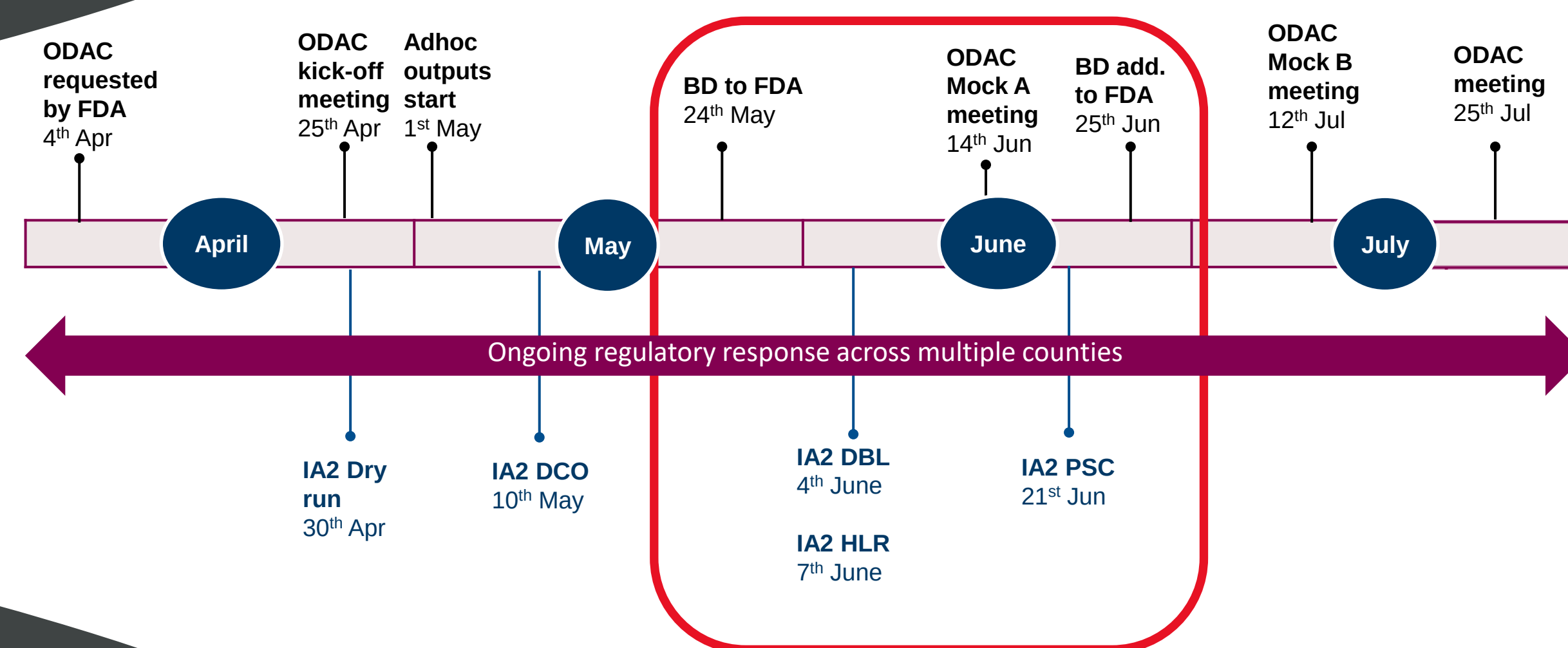


- Preparation began by mapping out slides to be prepared for questions that could be asked by the FDA during the ODAC Q&A. For every slide, there were multiple adhoc requests required
- There was the additional complexity of providing outputs across multiple data cuts. We needed to create outputs from our 2nd IA data cut (June), in time for the ODAC meeting the following month
- This led to a crunch in the timelines highlighted in red below, which coincided with a shortage of resource as highlighted in the next section

- Mapping out resource for this period proved challenging with the orange line showing programming demand, and the grey line showing programming supply
- We leveraged programming resource from other teams, as well as using our programming vendors to make up the surplus demand

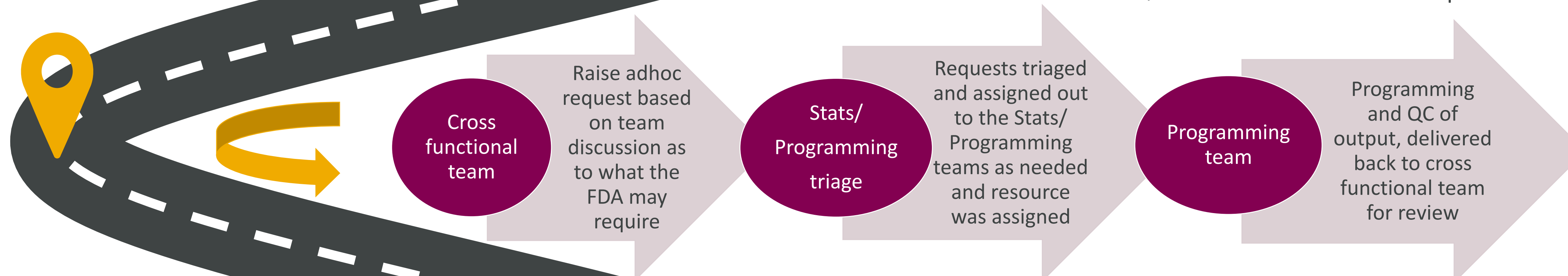


"Want to know what 865 adhoc requests look like? To the left are 425 outputs, just less than half of the overall ODAC preparation efforts..."



- Adhoc requests were raised by the cross functional team passed to Stats/Programming, where they were triaged, resourced and programmed
- Programming roles for the ODAC were changed from our normal day to day roles. Instead, they were geared to delivering the ODAC outputs as a priority, but making sure the vendor QA for our 2nd IA wasn't compromised

- Three months of programming work led to 865 adhoc requests being produced to support the creation of over 1000 slides for the ODAC meeting
- This worked out at one adhoc output being produced every 30 mins on average, every day, for three months



- In preparation for the ODAC, the team split across three areas, the bull pen, back room and programming room. The bull pen was where the speakers and responders were in the room with the FDA.
- The back room contained cross functional representatives, including programming, who managed and triaged any requests made during the ODAC.

- The programming room was where we had programmers and statisticians ready to action any requests for which we didn't already have a slide prepared.
- We held two mock meetings prior to the ODAC where we could test the communication and workflows between the three rooms, to simulate how a request would be addressed if needed during the ODAC.

- The ODAC took place at the FDA HQ, where both AZ and the FDA began with their opening presentations.
- The Q&A section focused on general perioperative trial designs. The discussion that followed deemed the trial was safe and effective, and another trial shouldn't be needed prior to approval
- The ODAC voted unanimously that peri-operative studies should account for contribution of phase for all future NSCLC trial designs
- The programming room and back room were not invoked during the ODAC meeting, owing to the fact that questions were well anticipated and addressed with adhoc requests prior to the meeting

- Three weeks later we achieved FDA approval...
"FDA approves neoadjuvant/adjuvant durvalumab for resectable non-small cell lung cancer"

Agenda:

- Call to Order and Introduction of Committee
- Conflict of Interest Statement
- FDA Opening Remarks
- Applicant Presentations: AstraZeneca UK Limited
- FDA Presentations
- Open Public Hearing
- Questions to the Committee/Committee Discussion

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

Yes	Vote: 11		
Ashley Rosko, MD	Azam Ghafoor, MD	Christopher Lieu, MD	Daniel Spratt, MD
David Mitchell	Jim Pantelas	Mark Conaway, MD	Pamela Kunz, MD
Ranjana Advani, MD	Ravi Madan, MD	Victor van Berkel, MD P...	
No	Vote: 0		
Abstain	Vote: 0		
No-Voting	Total: 0		

- Scan the QR code to watch the ODAC meeting as broadcast live on YouTube.
- Read my paper to get a more in-depth journey to the ODAC
- Attend my colleague Zach Dorman's presentation (SA03) on his ODAC experience



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