What if the data does not support the expected decision?

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Acknowledgement:
Thank you to
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What will you see today?

- How its supposed to be
- What if something goes wrong
- Importance of a cool mindset
- Making the pivot
- Happy ending

This is how it is supposed to be

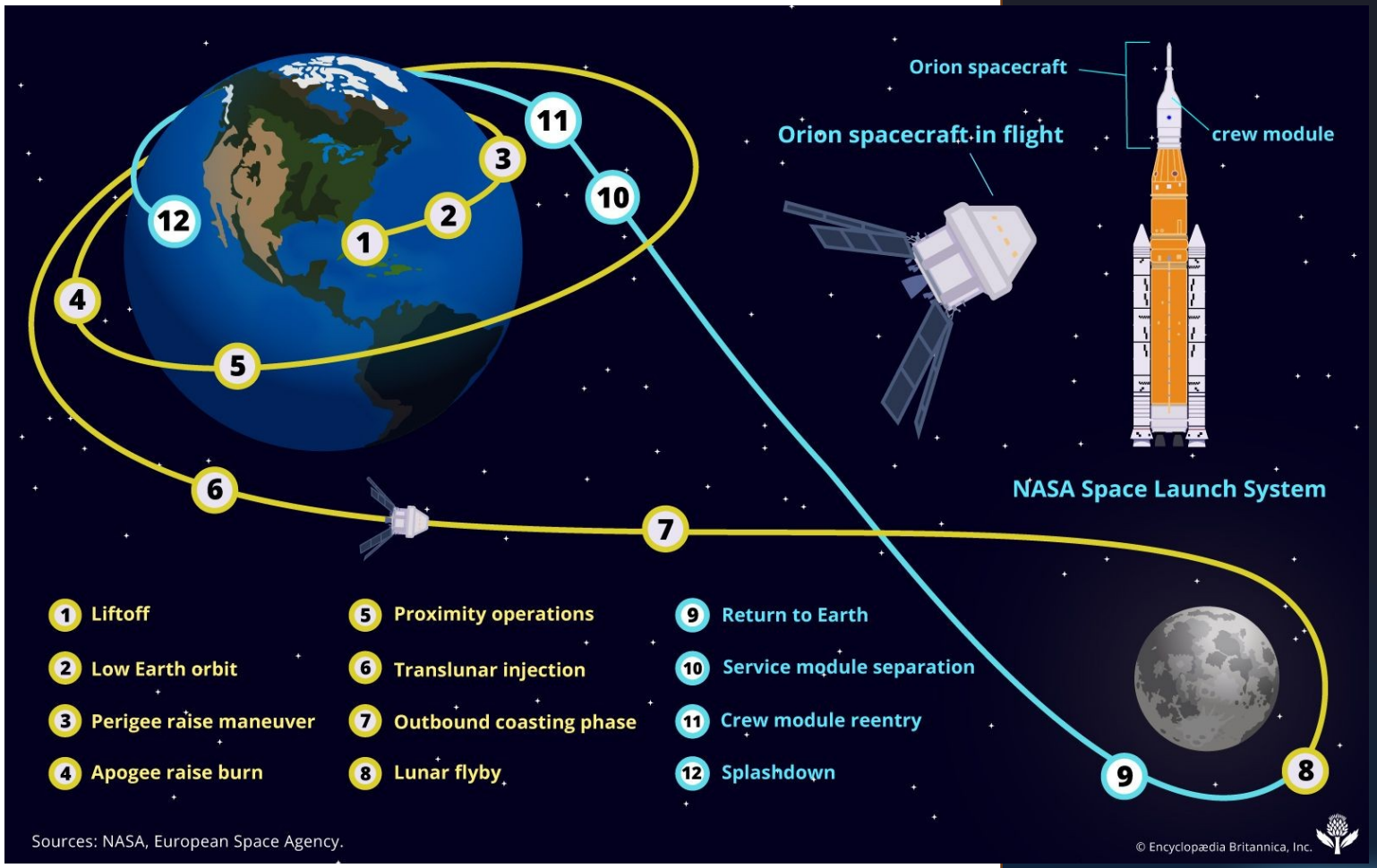
- All the rocket boosters fire up and we start the trial in record time, enrolling patients quickly and there are no immediate safety concerns



Everything runs smoothly during the main phase

- Patients turn up to visits on time, the events we want occur as expected, there are no unexpected AEs or safety concerns

... and then...



Touchdown! The treatment works as expected

EPHICACY





But, what if everything starts well…

- A surgical sealant that seals blood vessels quickly
- In tests it seals much quicker than alternatives

- **Success**: Sealing within 10 min. of restoring circulation

- **Expectation**: Higher % would seal within 10 min. than the alternative



….and something goes wrong?

- The data does not support the anticipated primary endpoint, jeopardizing a Premarket Approval (PMA) submission.
- Both sealants seal within 10 min. (time was too long!)



Importance of a cool mindset

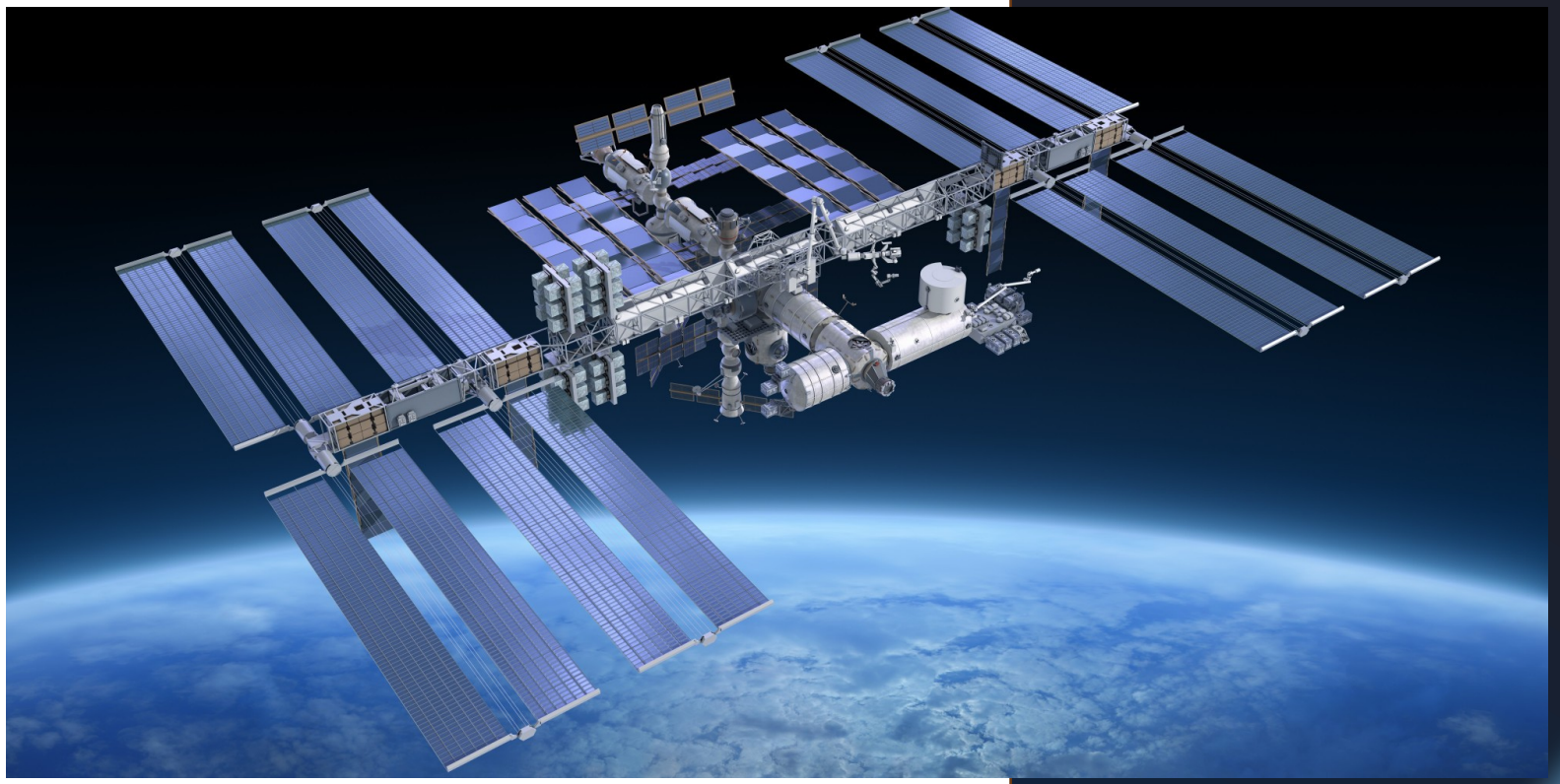
- The whole project team looked at the data, with a single focused mindset: how can we rescue this study?

- Key: No blame



Making the pivot

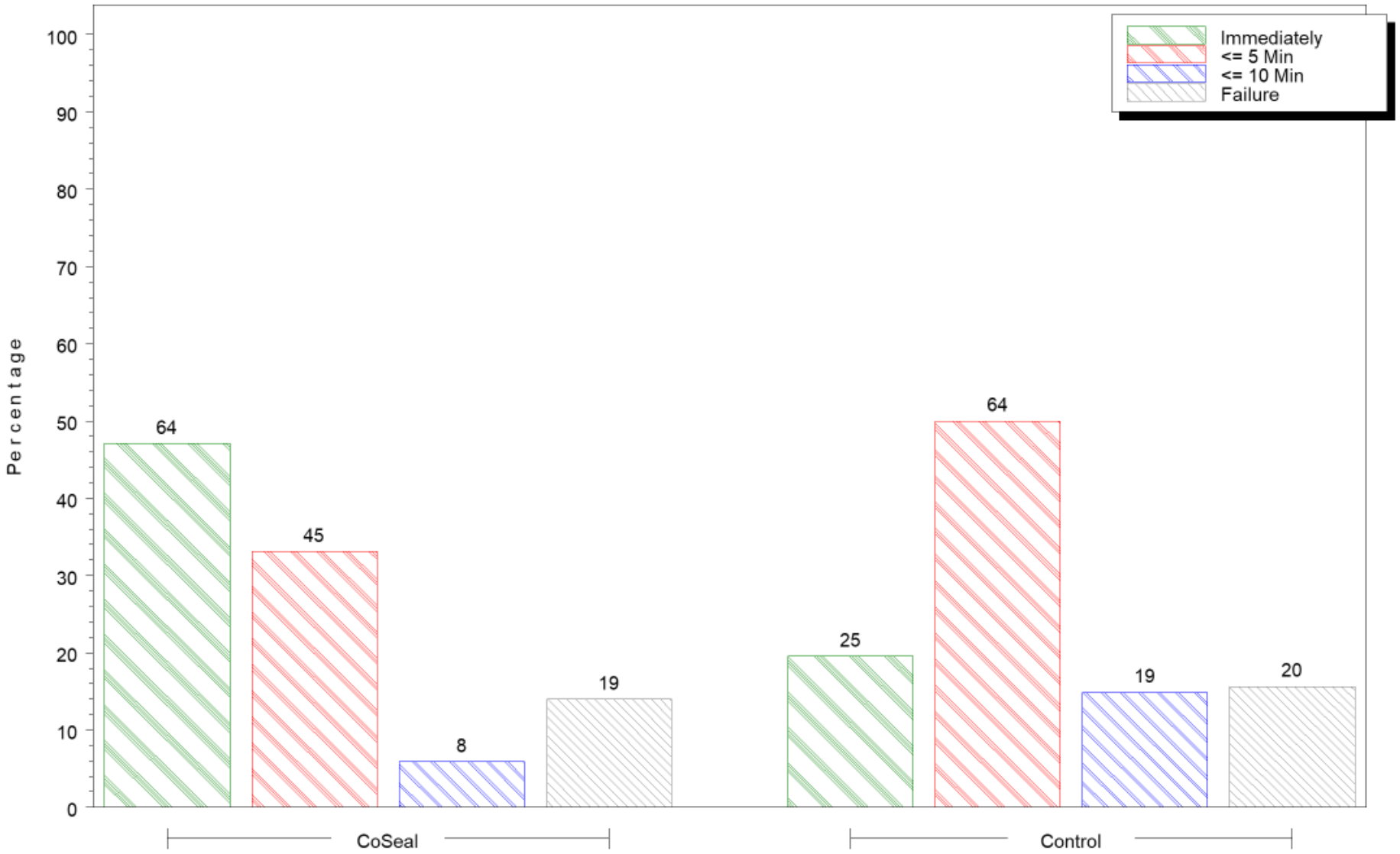
- Agree that primary Endpoint was flawed
- Explore the **totality** of the data
- Inquisitive mindset and flexibility led to identifying **new secondary endpoint**
- Extract meaningful insights



Making the pivot

- As the actual time when bleeding stopped was collected, **time to seal** showed almost half stopped instantly compared to 19% for the alternative!
- Median time to sealing was 16.5 sec. compared to 173 seconds for the alternative
- With this additional information, even though they had failed the primary objective of the study, they still were able to show FDA the superior performance of CoSeal over Control.

Figure 1: Device Performance - Time to Sealing
All Patients - All Sites



Note: Number of sites in category are indicated above corresponding bar.

Happy ending

- Successful Submission





Conclusion

- Comprehensive data collection enabled deeper analysis
- Collecting actual time (source data) rather than a tick-box to confirm sealed within 10 min. allowed further exploration
- Further data analyses and visualisation on the right data (collected by design) offered new opportunities

- **Open-mind** and looking at the **totality** of the data helped to discover new endpoint and convince the FDA.

Thank you

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