EFS: Value to Innovation

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Align. Achieve. Accelerate.

What was the Pathway for a Class III Device 7 Years Ago?

- FIM Outside the US, maybe outside EU
- Pre-CE Mark Study in the EU
- CE Mark Study in EU
- Use CE Mark data (partial or complete) to start a Feasibility Study in the US
- Commercialize in EU to financially support US pivotal
- US Pivotal Trial

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What was the Impact of the Pathway that existed 7 years ago?

- In the US, access to new medical technologies lagged the EU by more than 4 years
- Cutting edge medical device research all but left the US in search of a faster pathway for clinical research and market approval.
- Investment money left the medical device space in search of technologies that could make it to market faster and more predictably.

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EFS Arrived at the Most Opportune Time for MedTech

- Implant scandal in Europe has resulted tighter regulations.
- Germany has transitioned from a decentralized system to a centralized one….. Effectively shut down to early stage studies.
- Without EFS, there would be no reputable outlet for early stage investigation.
- Many Class III technologies would have ceased to exist.

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Benefits of the EFS Program: Value to Innovation

- Early access to reputable clinical sites
- Faster time to the single largest market in the world
- If company is based in the US, significant savings in travel cost and resource dilution
- Bring the FDA and CMS up to speed earlier, injecting more predictability into the future regulatory pathway

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Benefits of the EFS Program: Value to Innovation

- Accelerate overall timeline to market by leveraging US cases into the CE Mark pathway
  - No need to forsake the EU in favor of the US
  - Once the design is stable, US cases may be credited towards the CE Mark to accelerate approval times
  - Concept can apply to certain other countries as well

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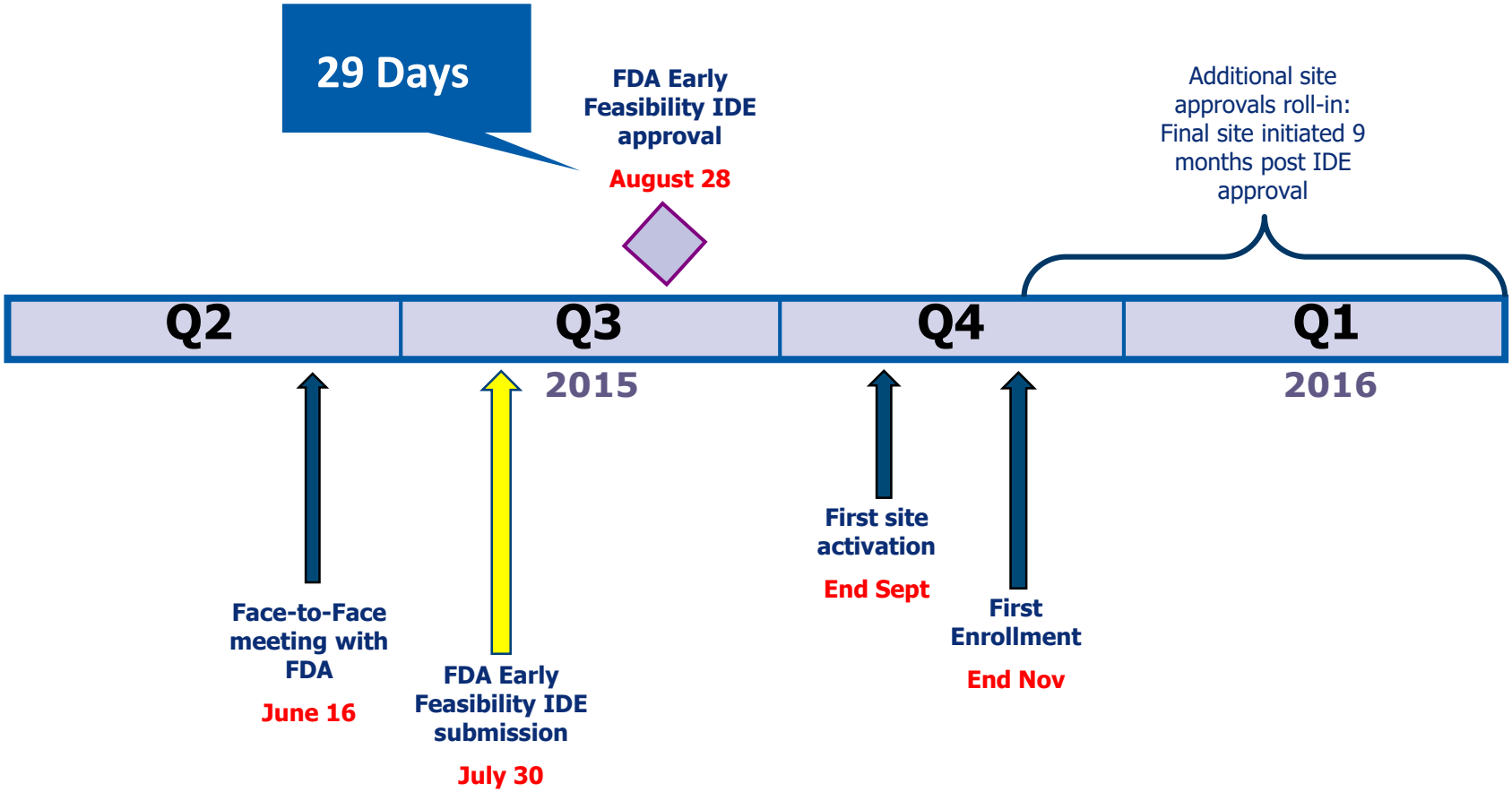
Trialign Case Study:
FDA EFS IDE Approval Timeline



A huge step forward on the front end,
a lot of work to be completed on the back end

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EFS: Value to US Innovation
The New Paradigm - When to Come to the US

- US Early Feasibility Study (EFS)
  - Could be your FIM (10—15 pts)
- US Extended Feasibility & CE Mark Combination
- US Pivotal Trial

Bottom Line: The US has once again become the place for early stage clinical research

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