Initiating clinical trials in Germany

Kardium

About Kardium

- Founded in 2007
- Developed device for treatment of atrial fibrillation
- Located in Vancouver, Canada
- ~100 employees

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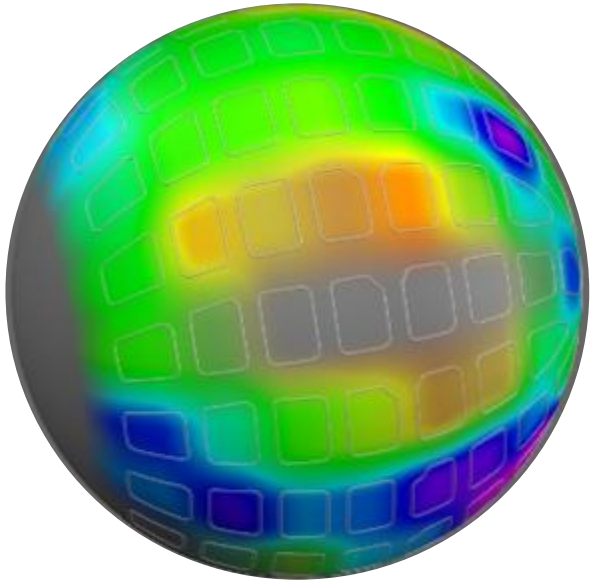
Globe® mapping and ablation system

Catheter

- Expanding 30 mm array
- 122 flat electrodes
- Every electrode can map and ablate



Software

- Detailed mapping
- Ablation selection
- Ablation control

RF Generator

- Controls all electronics
- 24 simultaneous ablations

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CE pre-market study

- Prospective · single-arm
- 2 centers = 1  + 1 
- 60 patients · 16 in Germany
- Endpoints
  - Primary: SAE rate @ 7 days
  - Secondary: Acute PVI · freedom from AF out to 1 yr

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Why Germany?

- Initial product launch in Europe
- Germany will be an important market
  - High procedure volume
  - Good reimbursement rates
  - Pathways for reimbursement of innovative devices
- Germany has good clinical trial infrastructure
  - Excellent research hospitals
  - Globally recognized doctors
  - Hospitals experienced with new medical devices

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Selecting our partners

- Submitted protocol with 3 German centres
  - Herzzentrum Leipzig
  - Herzzentrum Dresden
  - Cardioangiologisches Zentrum Bethanien – Frankfurt
- Selection criteria – wanted Doctors who
  - regularly publish and present influential research
  - have experience working with new devices
- Recruitment
  - Met with doctors early, during development of device
  - Regular meetings to update them on our progress

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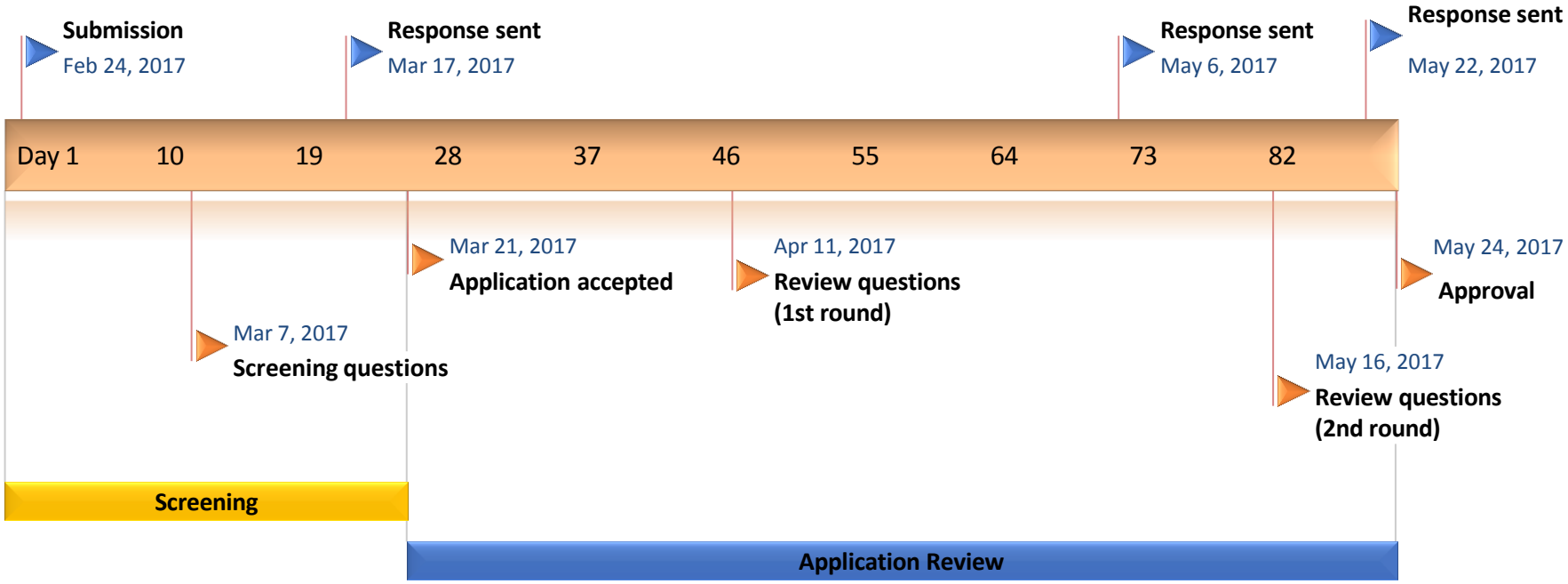
Clinical trial approvals in Germany

- 2 separate submissions
  - BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
  - Ethics Committees
- Centralized submission, all online (https://www.dimdi.de)
- Need to nominate a coordinating Ethics Committee

BfArM timeline



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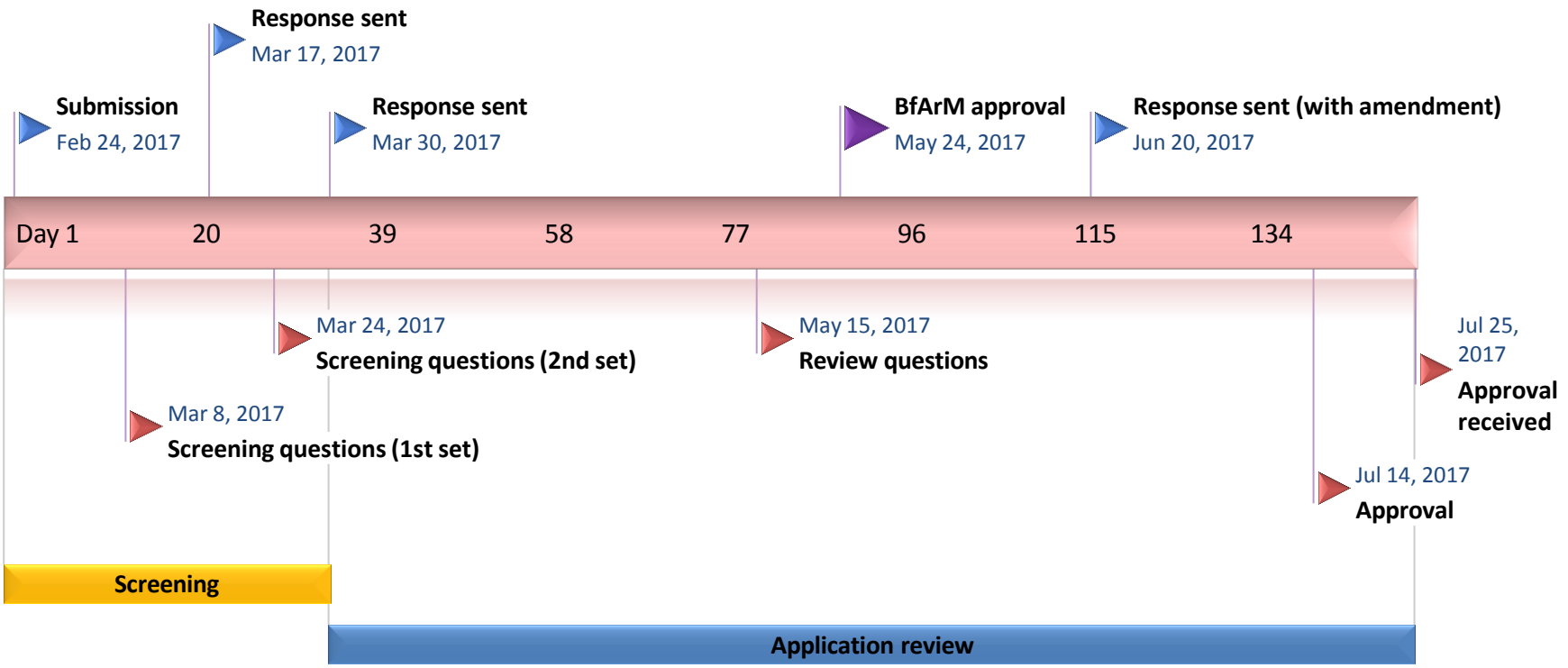
EC timeline



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Our experience in Germany

- It has been a very rewarding partnership
  - Doctors were excellent and highly skilled
  - Hospital staff were great to work with and very supportive
  - Knowledgeable study monitors
- The project went very smoothly
  - Good experience with regulators
  - Site initiation went very well, even without German speakers on the team
  - Logistics were easy (shipping, customs, accommodation)

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GTAI

- Highly recommend contacting GTAI when you start planning your project in Germany
- Have received advice on many topics
  - Device reimbursement
  - Labour laws and employment contracts
  - How and when to setup a German entity
- Provide detailed and useful information

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Contact information

Stefan Avall

Product Manager, Kardium Inc.

+1-604-248-8891 ext. 285

stefan.avall@kardium.com

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