Opportunities for Interactions with FDA: CDER and CDRH Perspectives

FDA Small Business
Regulatory Education for Industry (REdI)
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Background - Devices

- Many opportunities exist to interact with FDA throughout the medical product life cycle

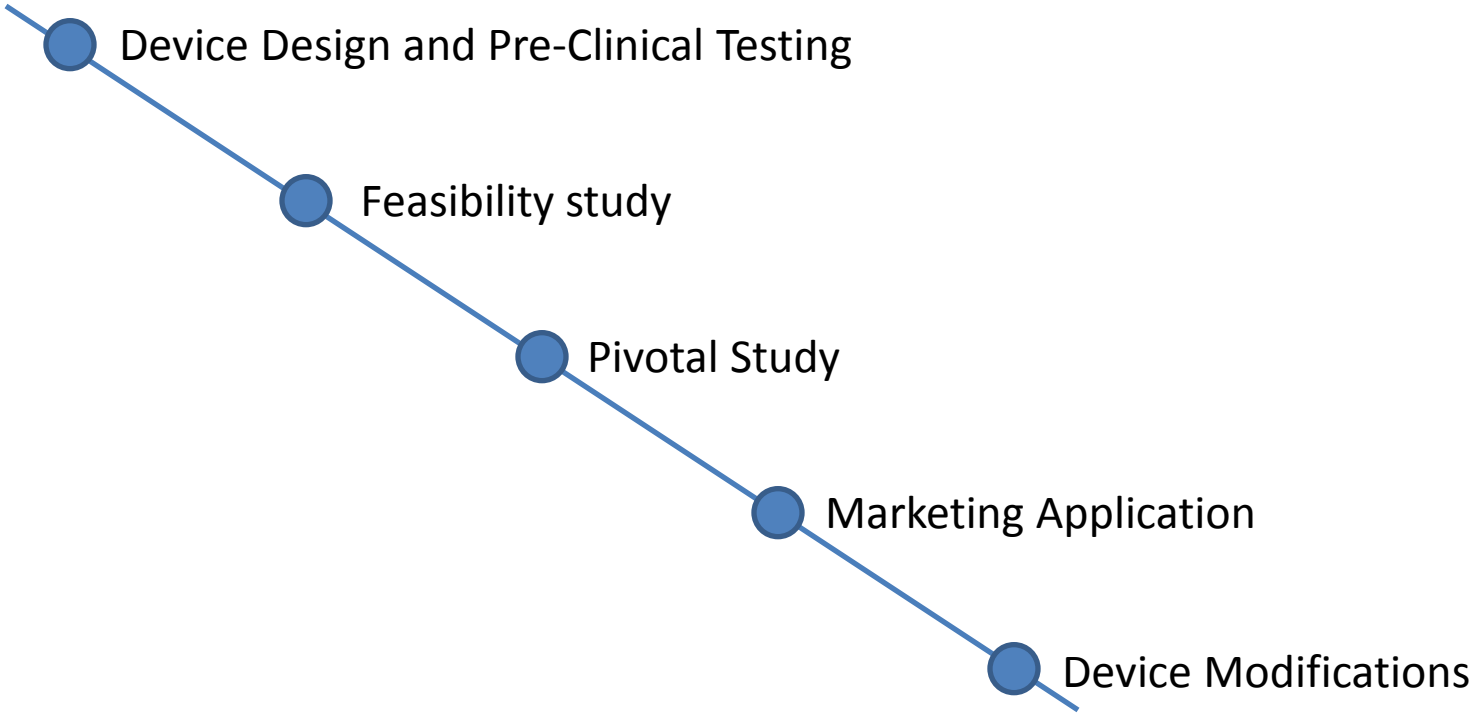
- Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) published guidance in February 2014:

  Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff

Q-Submissions (Q-Subs)

Q-Submission Type	Meeting	Timeframe for Meeting/Teleconference (from receipt of submission)
Pre-Submission*	Upon request	75-90 days**
Informational Meeting	Yes	90 days
Study Risk Determination	No	N/A
Agreement Meeting	Yes	30 days or within time frame agreed to with sponsor
Determination Meeting	Yes	Scheduled within 30 days of request
Submission Issue Meeting	Yes	21 days
Day 100 Meeting	Yes	100 days (from filing of PMA)

Typical Device Life Cycle



Meetings with CDER/CBER

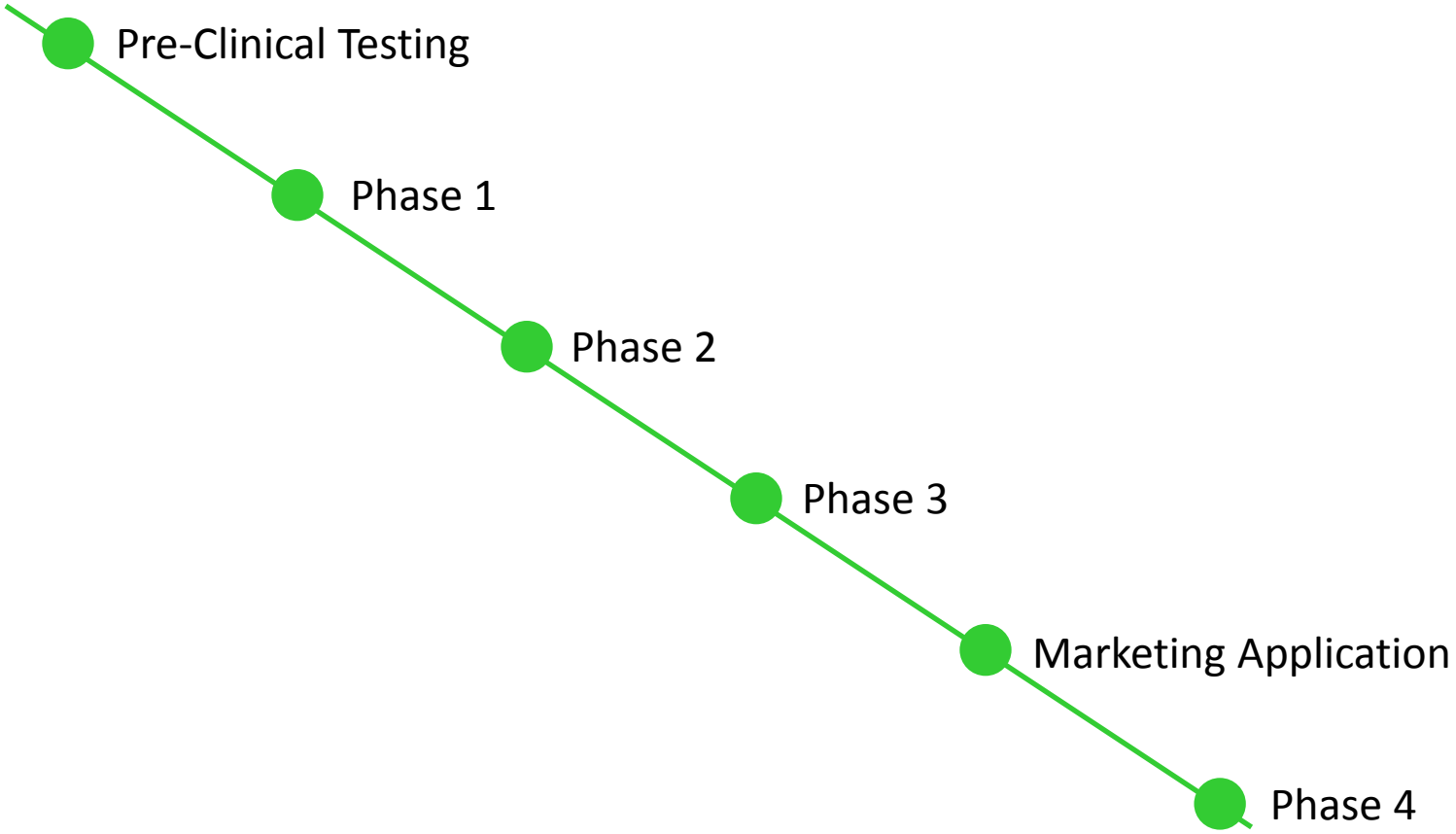
- Guidance for Industry, “Formal Meetings with Sponsors and Applicants for PDUFA Products”
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079744.pdf

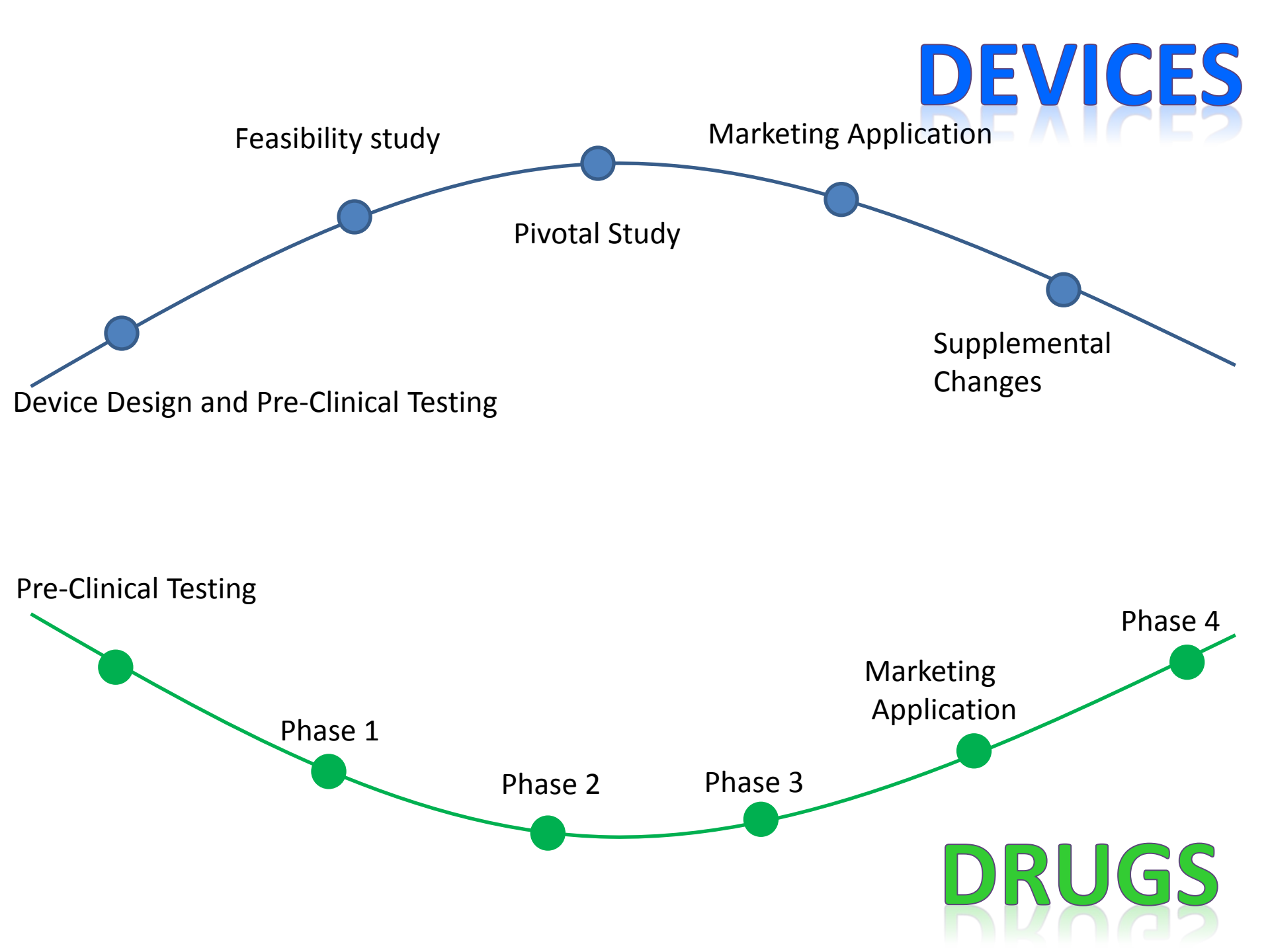
Types of Meetings

Type	A	B	C
Confirmation of scheduling	14 days	21 days	21 days
Held no later than	30 days	60 days	75 days
Briefing package	With meeting request	1 month	1 month
Description, Comments	Dispute resolution, Clinical holds, Special Protocol Assessment (SPA), Post action meeting (3 months of the action)	preIND^, EOP1, EOP2, Pre NDA/BLA, REMS* or PMRs**	Any other than type A or B Can be granted as written response only (WRO)

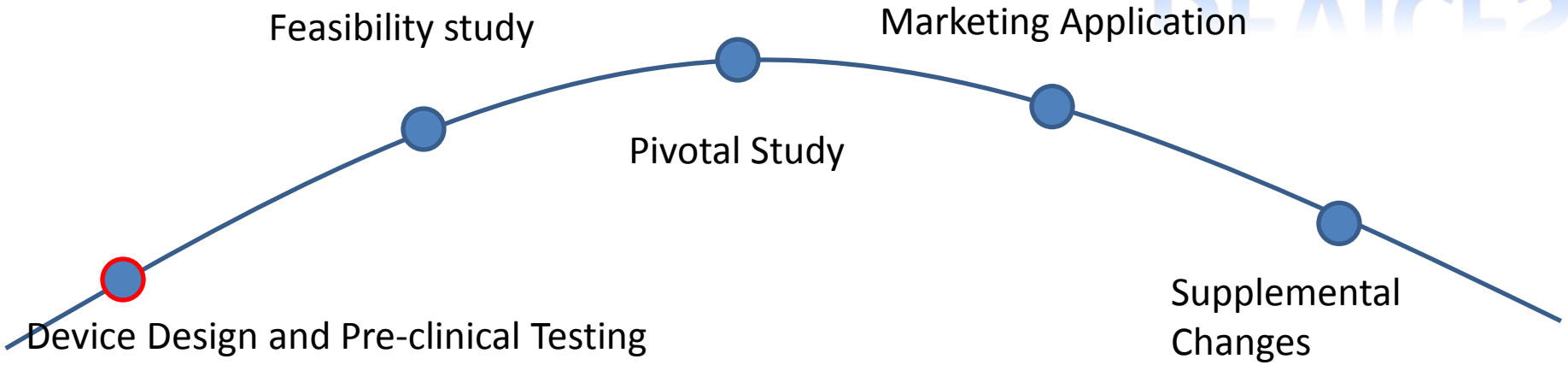
*Risk Evaluation and Mitigation Strategy ** Post Marketing Requirements ^ can be granted as WRO

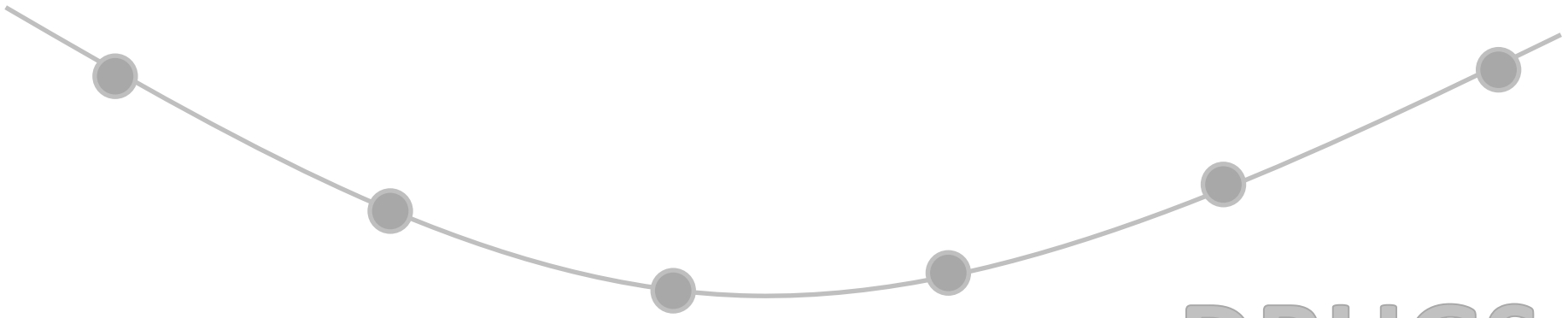
Typical Drug Life Cycle




DEVICES
Feasibility study
Marketing Application
Pivotal Study
Supplemental Changes
Device Design and Pre-Clinical Testing
Pre-Clinical Testing
Phase 4
Marketing Application
Phase 1
Phase 2
Phase 3
DRUGS

DEVICES

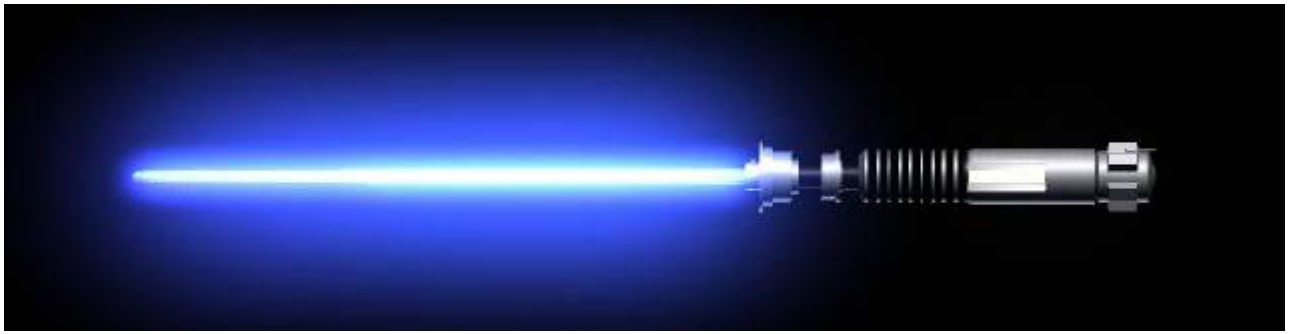




DRUGS

DEVICES

Case Study: Phototherapy, Inc. is expanding their product line after partnering with Jedi Devices to add light-saber based technology to their family of pain treatment products. They would like an opportunity to introduce FDA to this technology prior to starting discussions on non-clinical and clinical study requiremetns.



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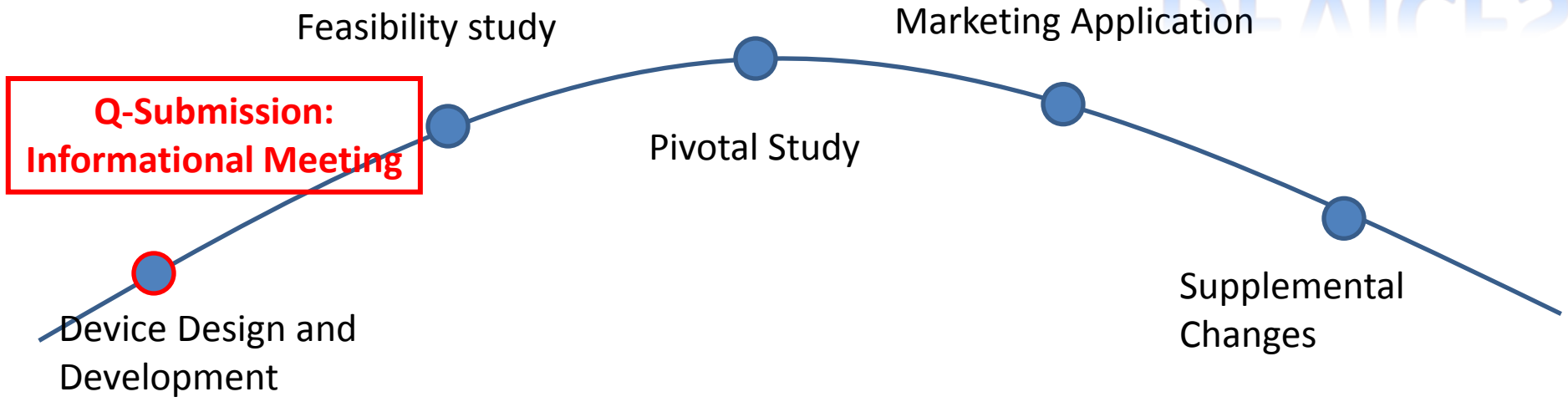
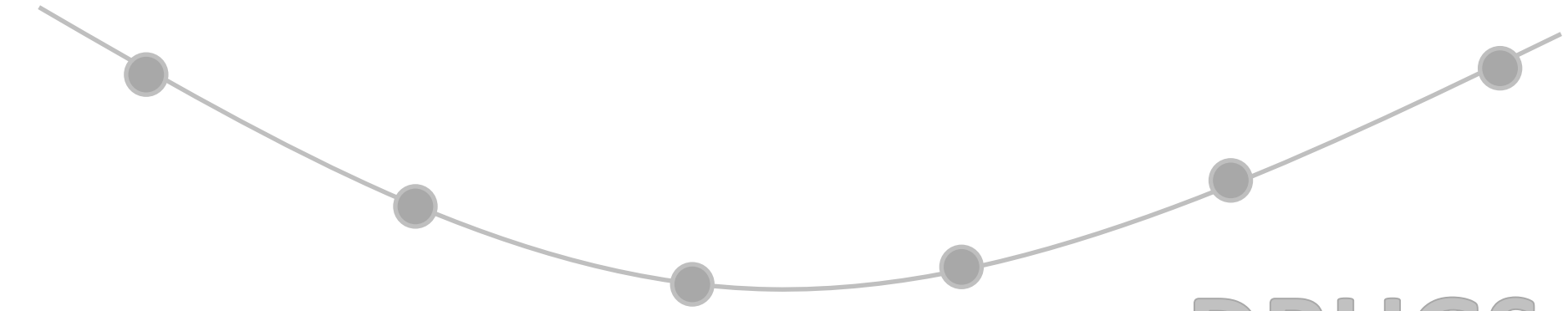




DRUGS

Informational Meeting

- Intent is to share information with FDA
  - Provide an overview of ongoing device development when there are multiple submissions planned within the next 6-12 months
  - Familiarize the review team about new device(s) with significant differences in technology from currently available devices.
- NO expectation of feedback, although review team may ask questions or offer suggestions if appropriate
- Granted as resources allow
- If granted, should be scheduled within 90 days

Informational Meeting: How to Request

- Submit a package that includes:
  - Cover letter identifying request type (Informational Meeting)
  - Brief statement of purpose, scope, or objectives of meeting
  - Proposed agenda with topics and time estimates
  - Three or more preferred dates
  - Planned attendees
  - A/V needs

What happens next?

- Sponsor submits to DCC
  - Assigned Q-number as Qyyxxxx (e.g. Q140001)
- CDRH reviewing division is assigned Q-sub
- FDA conducts acceptance review
  - Within 14 days, request is accepted or rejected (e-mail notification)
- FDA/Sponsor schedule meeting to occur (90 days)
  - Meetings are typically one hour

What happens next?

- Meeting occurs
- FDA in listening mode

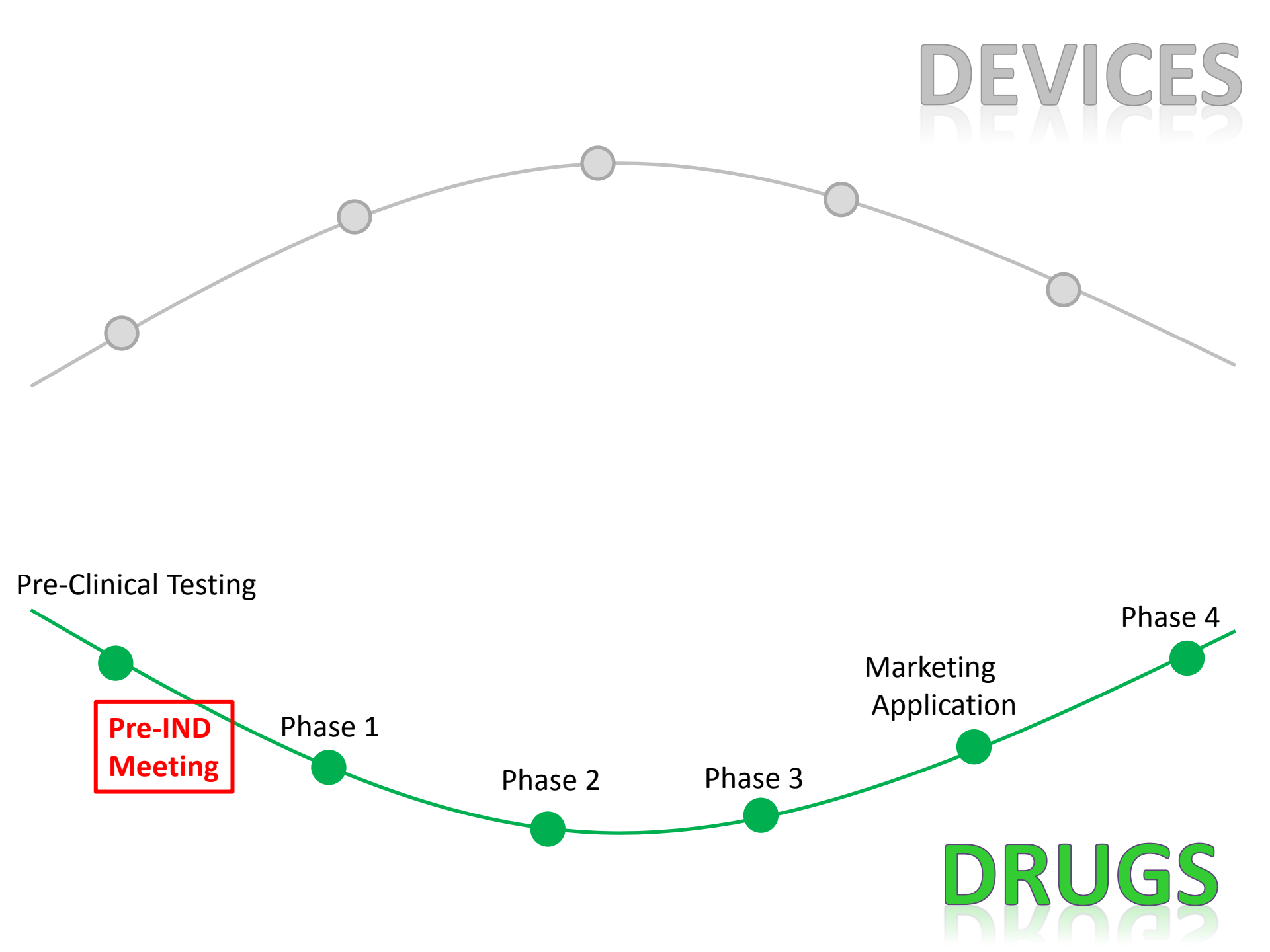
What happens next?

- After meeting, sponsor submits draft meeting minutes as Amendment to Q-sub
- FDA review team reviews within 30 days
  - If edits needed, FDA will send back to sponsor (via email)
- After 15 days, FDA-edited version becomes final, unless:
  - Sponsor submits meeting minutes disagreement amendment
    - Teleconference held and minutes resolved or agree to disagree

Case Study

- EYE LABORATORIES
  - Foreign company, ophthalmology expertise
  - Licensed the product from OnCO Therapeutics (oncology indication)
  - Conducted pre-clinical work
- Would like to submit an IND in US with a Phase 1 trial (FIH)
- Discuss and obtain concurrence on the content and format of your IND submission

DRUGS


DEVICES
Pre-Clinical Testing
Pre-IND Meeting
Phase 1
Phase 2
Phase 3
Marketing Application
Phase 4
DRUGS

Pre-IND Meeting

21 CFR 312.82 (a)-Early Consultation

- To review and reach agreement on the design of animal studies needed to initiate human testing
  - Do the dose and duration of the completed animal studies support the planned study?
  - Safety of new excipients
  - Impact of the currently available clinical data

Pre-IND Meeting

- To discuss the scope and design of your next planned clinical study
  - Sample size, study design, endpoints, statistical considerations
  - Safety Monitoring

Pre-IND Meeting

- To discuss the adequacy of the CMC information in support of the initiation of your clinical program
  - Manufacturing processes and in-process controls, both for drug substance and drug product
  - Tests and specifications for the drug product
  - Chemical compatibility of the excipients
  - Necessary data on drug product to assure stability during the planned clinical studies

Pre-IND Meeting

- To discuss the best approach for presentation and formatting of the information and data
  - Proposed IND cross referencing information
  - Letter of authorization
  - Literature references
  - Paper vs electronic

Pre-IND Meeting

- To discuss different regulatory programs
  - Breakthrough Therapy
  - Fast Track Designation
  - Orphan Product Designation
- To discuss plans for studying the drug product in pediatric population

How do I submit a Pre-IND Meeting Request

- Know your IND Division
  - CDER-Assigns Divisions by endpoints
- All pre-IND submissions addressed directly to the Chief Project Management Staff (CPMS) or other designated personnel until a PIND file is opened
  - http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/UCM166356.pdf

What happens next?

- A Pre-IND number is assigned and a file is opened
- A Regulatory Project Manager (RPM) is assigned
- An acknowledgment letter is issued
- No regulatory prerogatives
  - No US clinical studies can be conducted under the PIND
  - No FDA Form 1571 is needed
  - No US representative is needed, although encouraged

Pre-IND meetings are Type B meetings

- Meeting can be addressed as
  - Teleconference or Face to Face-Meeting to be scheduled by day 60 from the receipt date

- Written Responses Only
  - Requested by Sponsor or Initiated by FDA
  - Written responses provided by day 60 from receipt date

Pre-IND Meetings

- RPM will coordinate and communicate the meeting response
- Notification granting or denying the meeting is issued by day 21 from receipt
- Submit briefing documents at least 1 month in advance of the meeting/goal date

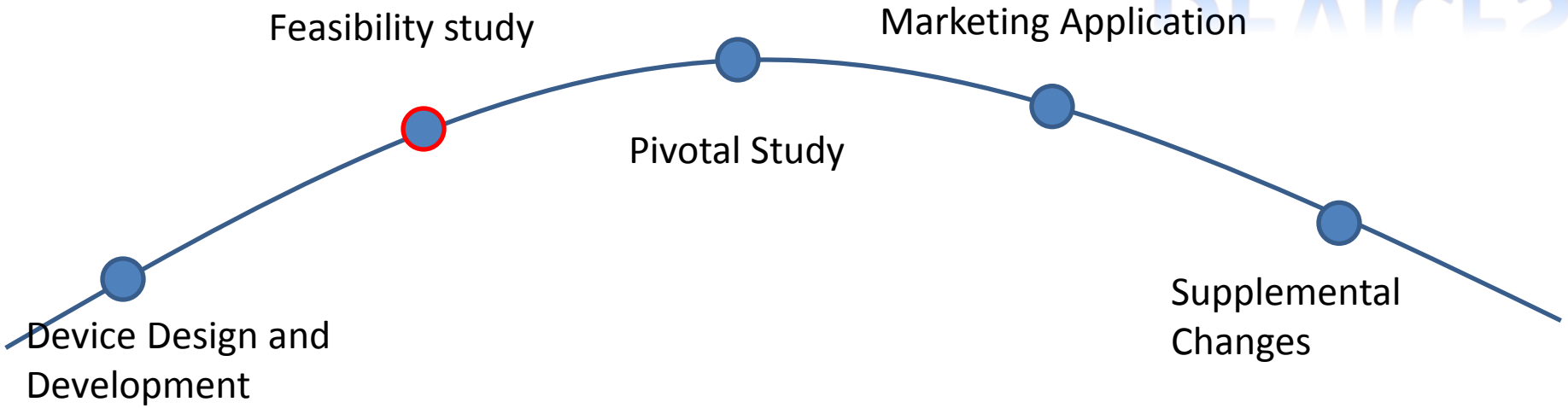
At the conclusion of this pre-IND meeting…

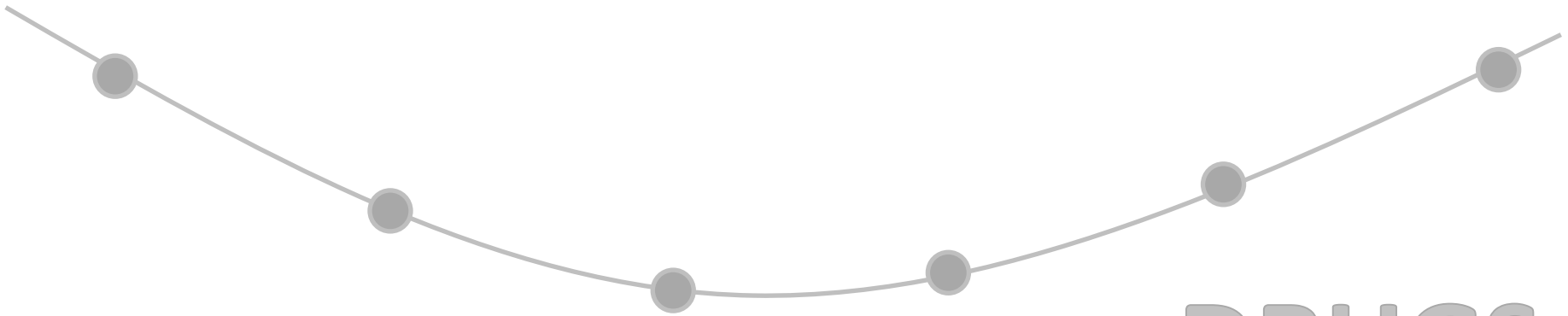
- FDA agreed that plan for the pre-clinical studies is acceptable but the adequacy is a review issue
- FDA agreed on the proposed clinical study synopsis
- LOA from OnCo Therapeutics
- Mixed submission (paper/electronic)
- Literature references
- EYE LABORATORIES might be requesting Fast Track designation

Pre-IND Meetings (When, Why)

- Novel indication
- No current Guidance Documents
- Unique molecular entity, studies or indications
- New sponsors or new to area of drug development
- Problematic Pharm/Tox signals
- NME
- Avoid protocol changes

DEVICES



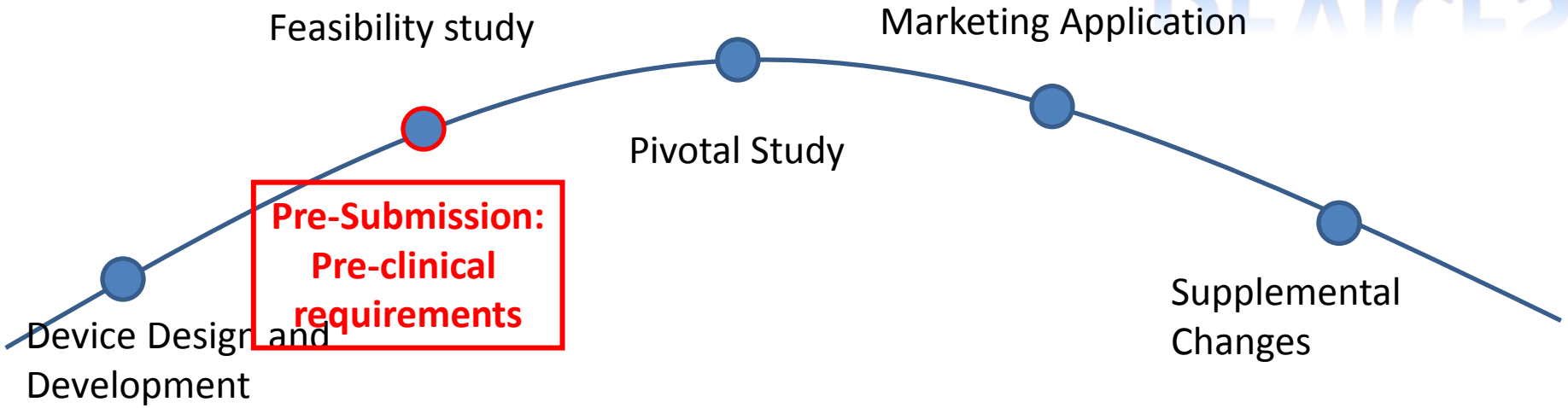


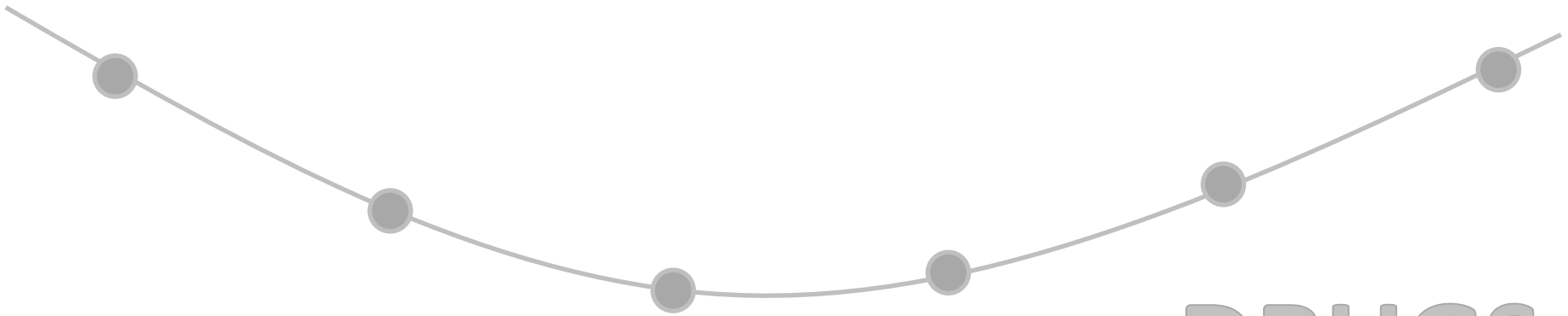
DRUGS

DEVICES

Case Study: Jedi Devices is developing their Light Saber Ablation Technology. Jedi Devices would like to discuss what initial pre-clinical testing is needed to demonstrate initial safety for conducting an early feasibility study?

DEVICES





DRUGS

Pre-IDE ⟹ Pre-Submission

- Pre-Investigational Device Exemption (Pre-IDE) (est. 1995) - mechanism for sponsors to obtain FDA feedback on future IDE applications prior to their submission.
- Pre-IDE evolved to include other device submission program areas:
  - Premarket notifications (510(k))s
  - Investigational Device Exemption (IDE) applications
  - Premarket approval (PMA) applications
  - Humanitarian Device Exemption (HDE) submissions
  - Evaluation of Automatic Class III Designations (de novo petitions)

Definition of a "Pre-Sub"*

- A formal written request from an applicant for feedback from FDA
  - formal written response
  - meeting or teleconference in which the feedback is documented in meeting minutes
- When FDA's feedback on specific questions is necessary to guide product development and/or application preparation
- Request must include specific questions regarding review issues relevant to a planned IDE or marketing application

*From the MDUFA III Commitment Letter

FDA Feedback on a Pre-Sub

- Feedback represents FDA's best advice based on the information provided
- FDA intends to stand behind our feedback unless:
  - Information in subsequent submission is not consistent with Pre-Sub
  - Data in the subsequent submission raise important new issues related to safety and effectiveness
  - New issues materially relevant to a determination of safety or effectiveness that have emerged since the time of the Pre-Sub

Pre-Submission Meeting: How to Request

- Submit a package that includes:
  - Cover letter identifying request type (e.g. Pre-Sub for an IDE)
  - Table of Contents
  - Device Description and indications for use
  - Previous Discussions or Submissions
  - Overview of Product Development
  - Specific Questions
  - Method of feedback
  - Meetings: Three or more preferred dates, planned attendees, and A/V needs

What happens next?

- Sponsor submits to DCC
  - Assigned Q-number as Qyyxxxx (e.g. Q140001)
- CDRH reviewing division is assigned Q-sub
- FDA conducts acceptance review
  - Within 14 days, request is accepted or rejected (e-mail notification)
  - If rejected, sponsor submits amendment with missing information and clock re-starts

What happens next?
3-Day Feedback

For Pre-Subs where the feedback is via a meeting or teleconference:

- FDA provides initial feedback at least 3 business days prior to meeting/telecon
  - complete response to question
  - partial response, noting that further discussion is needed
  - a request that the sponsor be prepared to discuss the question in more depth or to further explain the question
- If all questions are answered sufficiently, sponsor can choose to cancel

What happens next?

- Feedback provided (written or meeting/telecon) within 75 to 90 days.
  - FDA will attempt to schedule sooner if resources allow
- Meetings/telecons should generally be limited to 1 hour, but longer times can be requested with a rationale and granted if appropriate (e.g., complex product/issues)

What happens next?

- After meeting, sponsor submits draft meeting minutes as Amendment to Q-sub
- FDA review team reviews within 30 days
  - If edits needed, FDA will send back to sponsor (via email)
- After 15 days, FDA-edited version becomes final, unless:
  - Sponsor submits meeting minutes disagreement amendment
    - Teleconference held and minutes resolved or agree to disagree

Case Study Wrap up

Pre-Sub Package:

- Description of light saber ablation technology and proposed indications
- Device evaluation strategy
- Testing and preliminary results described
  - Mechanical
  - Electrical safety
  - Software validation
  - Human factors
  - 1 mo. animal study showing ability to ablate tissue

FDA review team:

- Mechanical engineer
- Electrical engineer
- Veterinarian
- Oncologist
- Surgeon with previous Jedi training
- Plasma specialist

Internal meeting held prior to meeting with sponsor

Sponsor Meeting

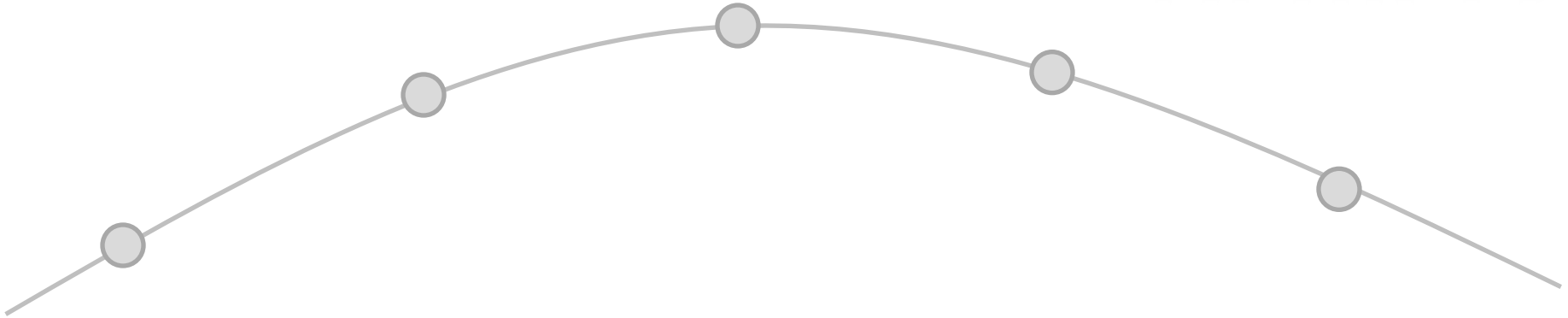
- 3-day Feedback provided following feedback
  - Mechanical testing and software validation plans appear appropriate
  - Additional discussion is needed on
    - training required by surgeons in using this technology
    - mechanism of action of energy shields that protect adjacent tissues from injury
    - long term effects of light saber plasma field exposure in terms of both safety and effectiveness
- Meeting between sponsor concluded additional animal and bench testing is needed prior to submission of an IDE

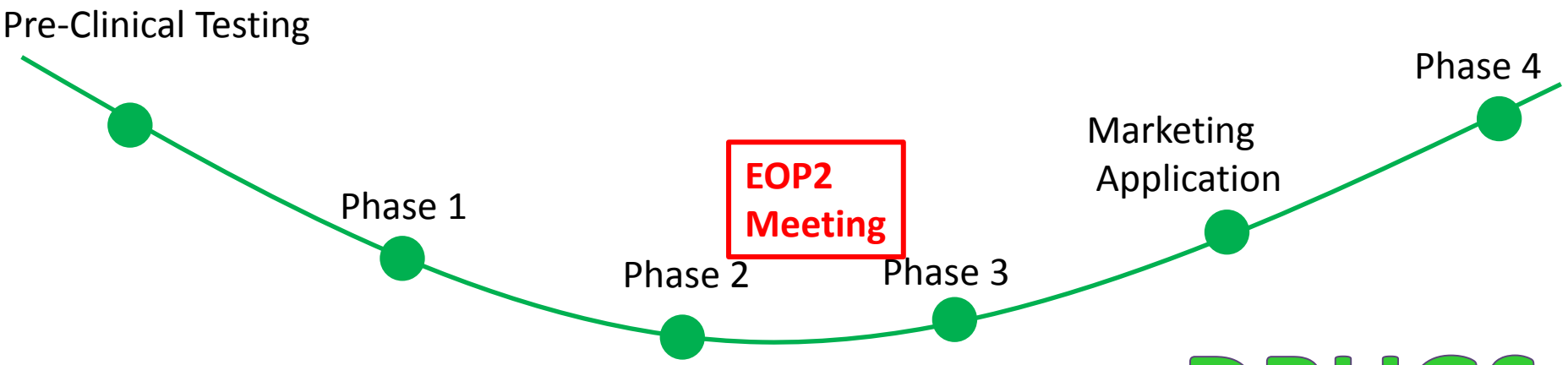
Case study continues…

- Completed Phase 1 and Phase 2 Studies
- Developed the clinical formulation
- Ready to start Phase 3 Trials
- Plan to request a waiver for Pediatric Studies

DRUGS

DEVICES





DRUGS

End of Phase 2 (EOP2) Meeting
(21 CFR 312.47 (b))

- To discuss Phase 1 and Phase 2 data
- To discuss protocols for Phase 3
- To discuss plans for Pediatric Studies
- To discuss required clinical pharmacology studies
- To discuss the status of the pharmaceutical development
- To discuss any additional information needed in support of an NDA/BLA

EOP2 Meeting

- Type B meeting
- Meeting request submitted to the file (Central Document Room)
  - Courtesy copy to the Project Manager
- Notification granting/denying the meeting issued within 21 days of receipt
- Face to Face or Teleconference scheduled within 60 days of receipt
- Briefing document to be received 1 month in advance of the meeting date

EOP2-CMC Meeting

- To evaluate CMC plans and protocols to ensure that meaningful data will be generated to support the marketing application.
  - Particularly important for New Molecular Entities (NMEs), biotechnology products, natural products, complex dosage forms and/or drug-device delivery systems.
  - Unique physicochemical(e.g. Polymorphic forms, enantiomers) and biological properties

EOP2-CMC

- To evaluate the status of the pharmaceutical development program to date
- To discuss approach to specifications (tests, analytical procedures, acceptance criteria), qualification of impurities
- To discuss the “to be marketed” formulation and the link between formulations and dosage forms used in preclinical, clinical, PK/PD studies and planned commercial formulations
- To establish appropriate dissolution test procedures
- To obtain concurrence on the “starting material” designation

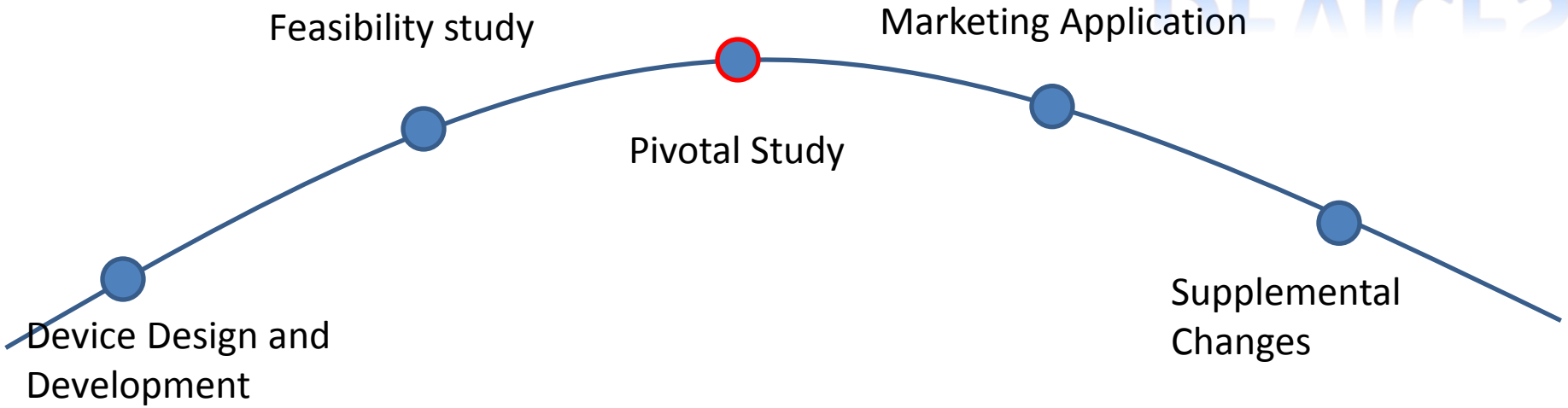
EOP2-CMC

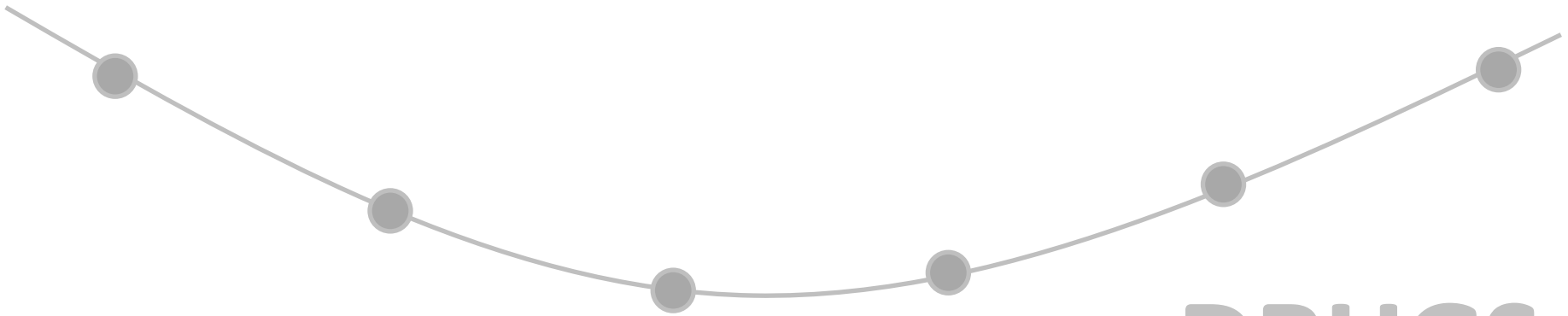
- To determine the stability data required for the NDA submission
- To discuss specific considerations for container/closure system components for specialized delivery systems such as metered dose inhalers, dry powder inhalers, disposable pen injectors, transdermal patches or other novel dosage forms
- To discuss the approach to sterilization process validation and/or container closure testing

At the end of the EOP2 meeting

- Division agreed with general Phase 3 plan
- Suggested the submission of an SPA
- Deferral instead of waiver for PREA
  - Remind to submit an iPSP (Initial Pediatric Study Plan)-60 days after EOP2 meeting
- Provided guidance on the stability protocols for clinical drug product

DEVICES

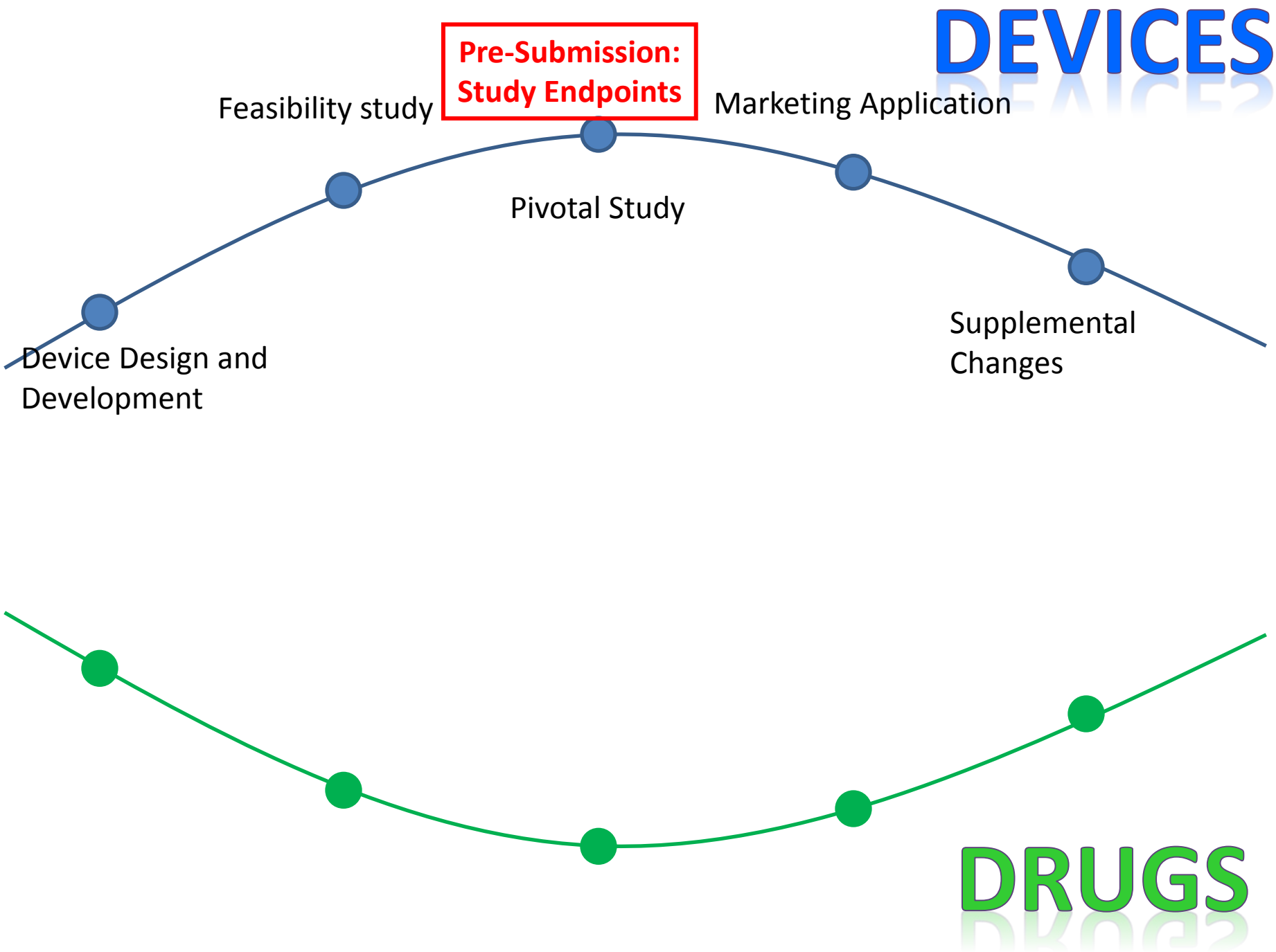




DRUGS

DEVICES

Case Study: Now that preliminary safety and effectiveness has been demonstrated for the Jedi Ablation System, what performance goals should be used to support the desired labeling claims?


DEVICES
Pre-Submission:
Study Endpoints
Feasibility study
Marketing Application
Pivotal Study
Device Design and
Development
Supplemental
Changes
DRUGS

Pre-Submission

- This scenario would follow the same pre-submission process previously outlined
- FDA review team may be different
- Background information in sponsor package may be different

Case Study Wrap up

Pre-Submission Package:

- Description of technology and proposed indications
- Brief summary of study design
- Proposal for safety and effectiveness performance goals
  - Clinical basis for performance goal
  - Statistical basis for performance goal

FDA review team:

- Oncologist
- Surgeon
- Statistician

Internal meeting held prior to meeting with sponsor

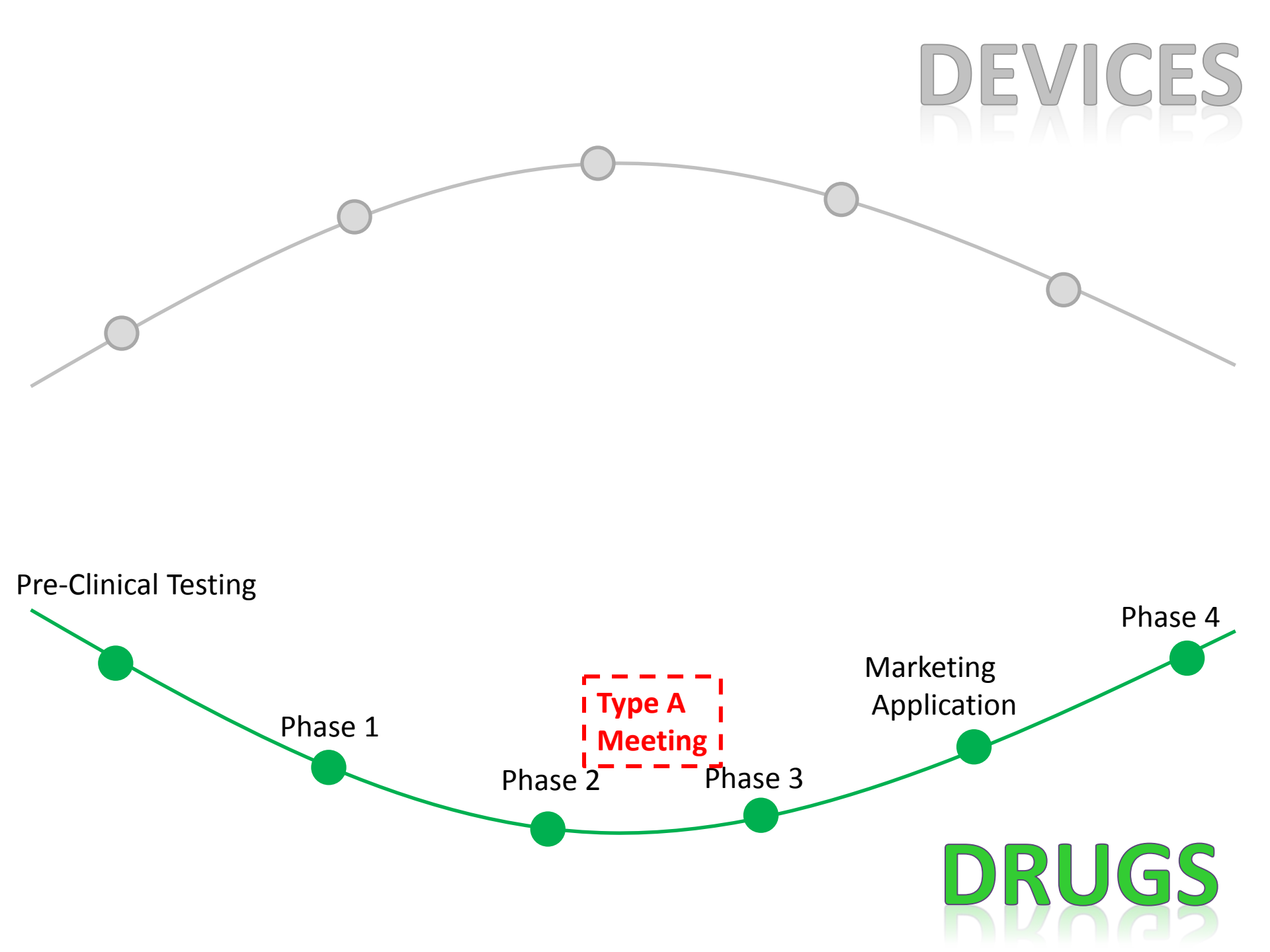
Sponsor Meeting

- 3-day Feedback provided following concern
  - The composite safety endpoint did not include the adverse event of stroke. Your animal study showed possibility of blood coagulation and thrombosis due to unintended blood exposure to light-saber plasma. Therefore, please include stroke in your composite endpoint and provide a statistically and clinically based rationale for a new proposed performance goal.
- Jedi Devices proposed a modified safety performance goal with statistical and clinical justification, which was discussed with FDA during the face-to-face meeting. It is not clear if mind control was used by the sponsor, however agreement was reached on the performance goals for Jedi Devices' pivotal study.

As the case study continues…

- SPA for the trial that will form the primary basis for an efficacy claim
  - Met with the Division regarding the development context of this protocol (EOP 2 meeting)
- SPA no-agreement letter describing issues related to the proposed statistical analysis
- Can request a Meeting with FDA

DRUGS


DEVICES
Pre-Clinical Testing
Phase 1
Phase 2
Type A
Meeting
Phase 3
Marketing
Application
Phase 4
DRUGS

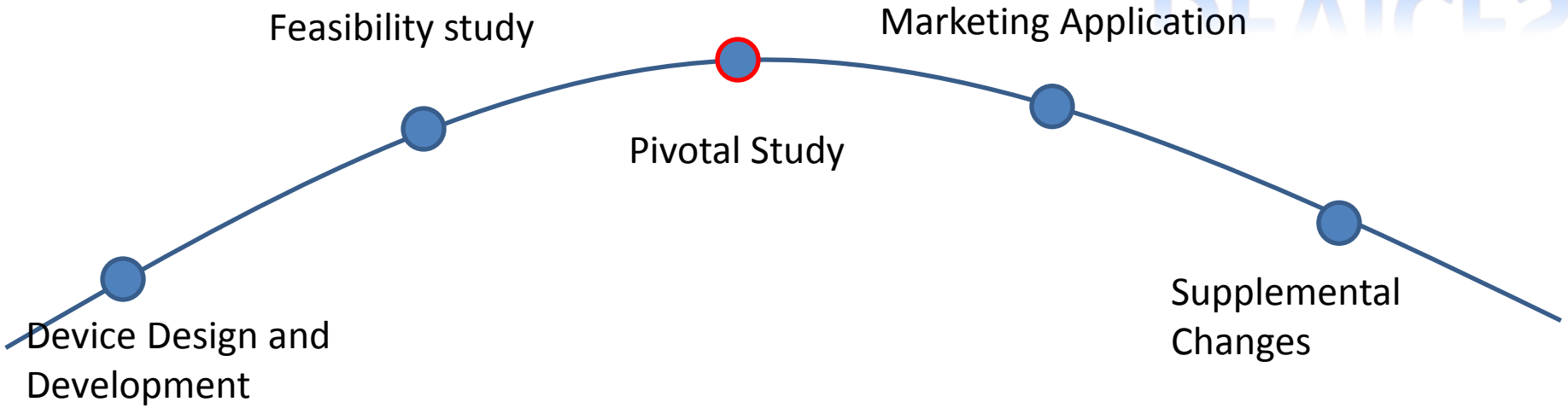
Type A Meeting

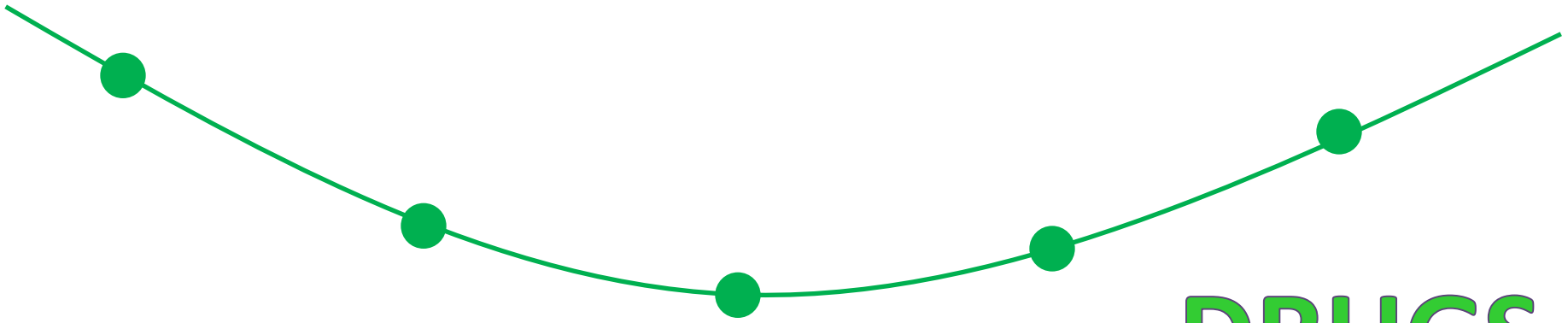
- Scheduled within 30 days from receipt date
- Notification of meeting granted/denied within 14 days after receipt of meeting request
- Briefing document accompanies the meeting request

Type A Meeting

- Immediately necessary for an otherwise stalled drug development program
  - Dispute Resolution
  - Clinical Holds
  - Special Protocol Assessments (not mandatory)
  - End of Review/Post Action meeting following a Complete Response letter
  - Difficulty enrolling pediatric patients to fulfill PREA

DEVICES

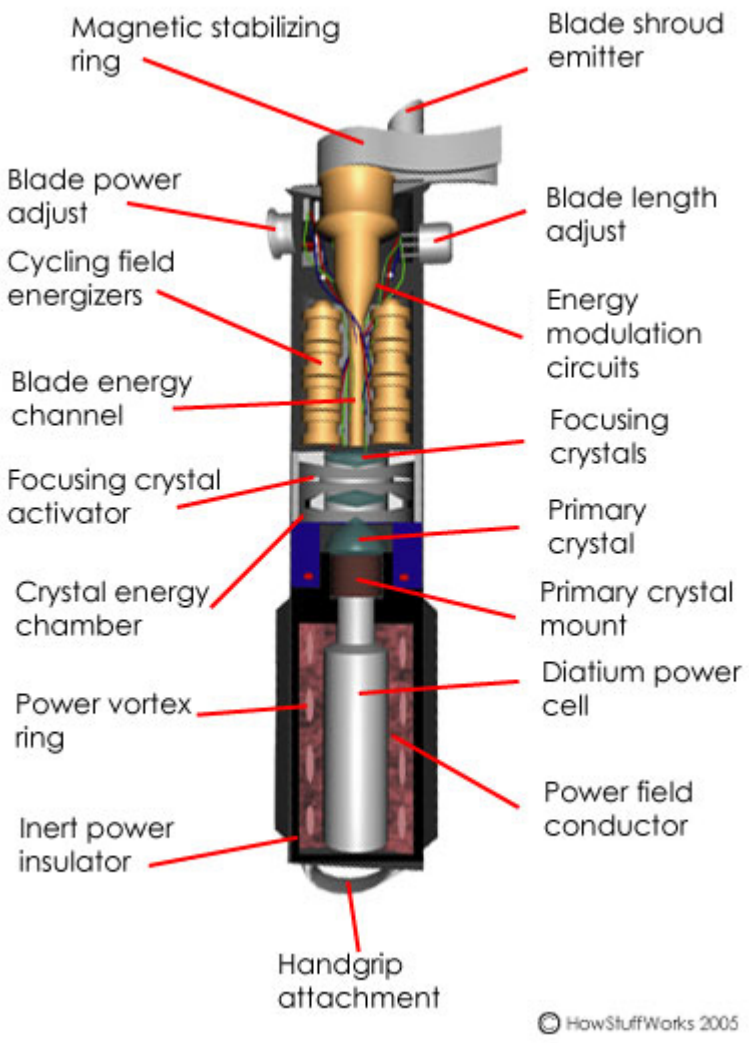


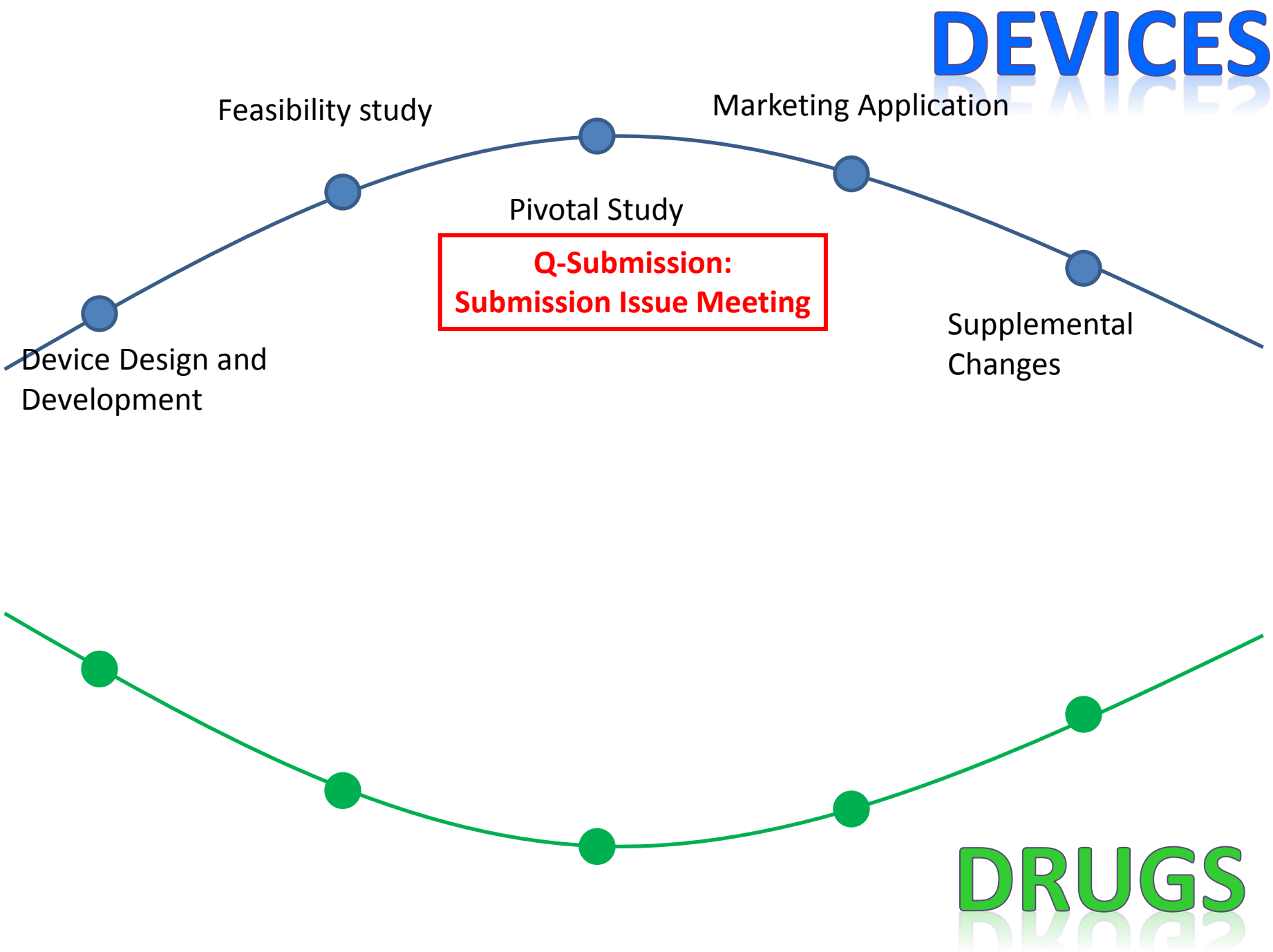


DRUGS

DEVICES

Case Study: Jedi Devices received a disapproval letter for the pivotal study and would like clarification on questions related to their electrical testing studies.




DEVICES
Feasibility study
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Submission Issue Meeting

- Related to an active submission (usually on hold)
- Meeting/telecon to discuss outstanding review issue
- Includes deficiencies communicated in writing (e.g., disapproval, additional information, or major deficiency) or through email, telephone, or fax (e.g., telephone hold).
- Meeting not intended for pre-review of planned responses, but instead to provide clarification of FDA's questions or to discuss an approach to responding to complex issues.

Submission Issue Meeting

- Needed when:
  - Review requires consultant and/or next level supervisor
  - In-person meeting is requested
  - Number/type of questions result in need to submit an agenda and/or materials to guide discussion
- Not needed for clarification questions that can be readily addressed by the lead reviewer by email or phone
- If a review of substantial new information (e.g., new/revised protocol) is requested, sponsor should submit a Pre-Sub instead

Submission Issue Meeting: How to Request

- Submit a package that includes:
  - Cover letter identifying request type (Submission Issue Meeting, referencing appropriate submission)
  - Brief statement of purpose, scope, or objectives of meeting – focused questions
  - Proposed agenda with topics and time estimates
  - Three or more preferred dates
  - Planned attendees
  - A/V needs

What happens next?

- Sponsor submits to DCC
  - Assigned Q-number as Qyyxxxx (e.g. Q140001)
- CDRH reviewing division is assigned Q-sub
- FDA conducts acceptance review
  - Within 14 days, request is accepted or rejected (e-mail notification)
- FDA/Sponsor schedule meeting to occur (21 days)
  - Meetings are typically one hour
- Same process as for other meeting types for meeting minutes

Case Study Wrap-up

- FDA Deficiency: Your electrical testing results included 3 out of 25 samples where output power was below your specification. However, you did not provide an explanation of these failures, or a justification for your conclusion that the results are acceptable. FDA is concerned that the power generated by your diatium power cell will be inadequate to consistently create effective lesions in the target tissue. Please justify the acceptability of your results, or provide additional testing/data to demonstrate that the output power of your devices is adequate for its intended purpose.

Teleconference Discussion

- Sponsor question: Based on our experience, the power generated even in the 3 failures is adequate to ablate tissue. Therefore, we have lowered our specification and plan to provide data from our in-vitro studies to show that there is an adequate margin for effectiveness at the lower limit of the specification. Is this approach adequate?

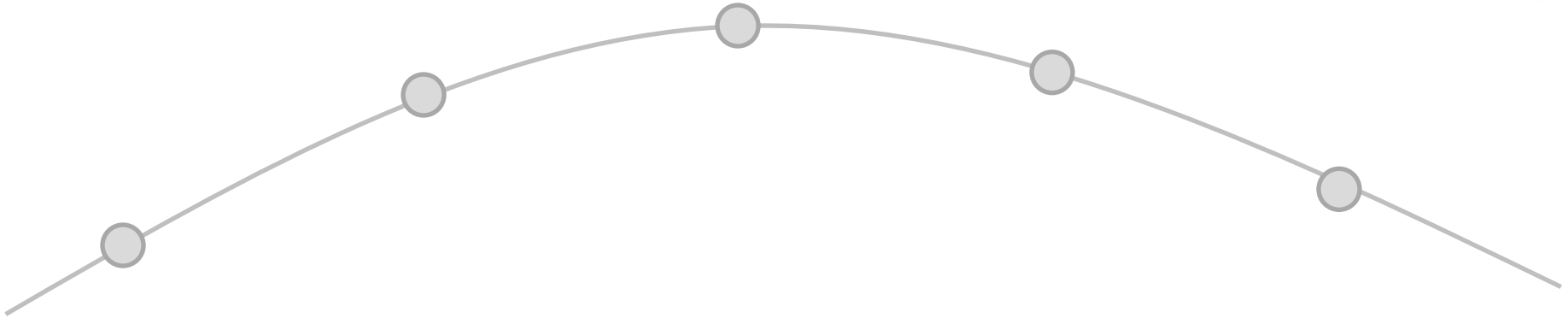
- Meeting Proceedings: After the sponsor explained how they validated the in-vitro studies, FDA indicated that this approach was likely adequate and asked that the sponsor provide all test protocols and reports in their response amendment.

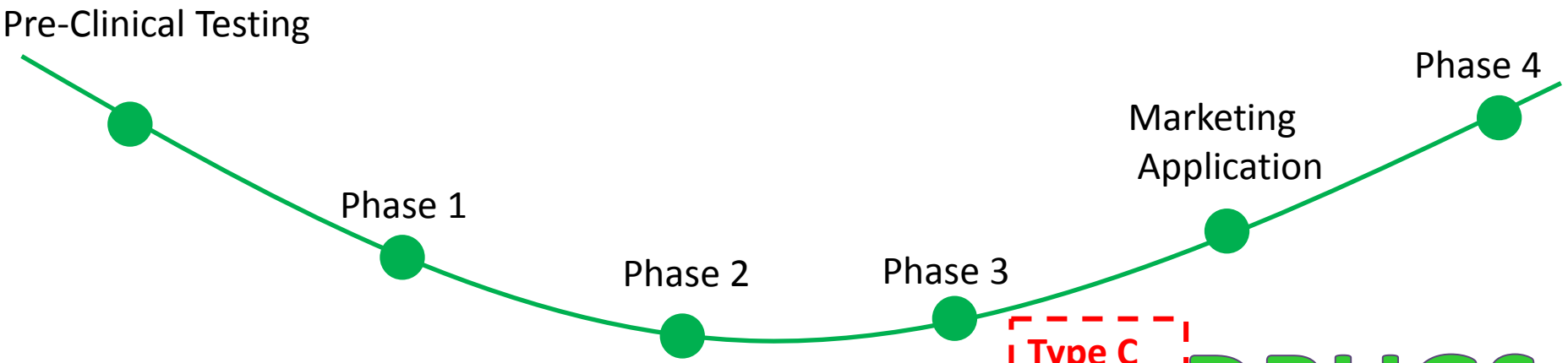
In this particular case study...

- IND is active, continue development of the product
- Obtain FDA guidance on the conduct of studies for a new indication
  - Trial design and statistical considerations
  - Endpoints
  - Size of safety database

DRUGS

DEVICES





DRUGS

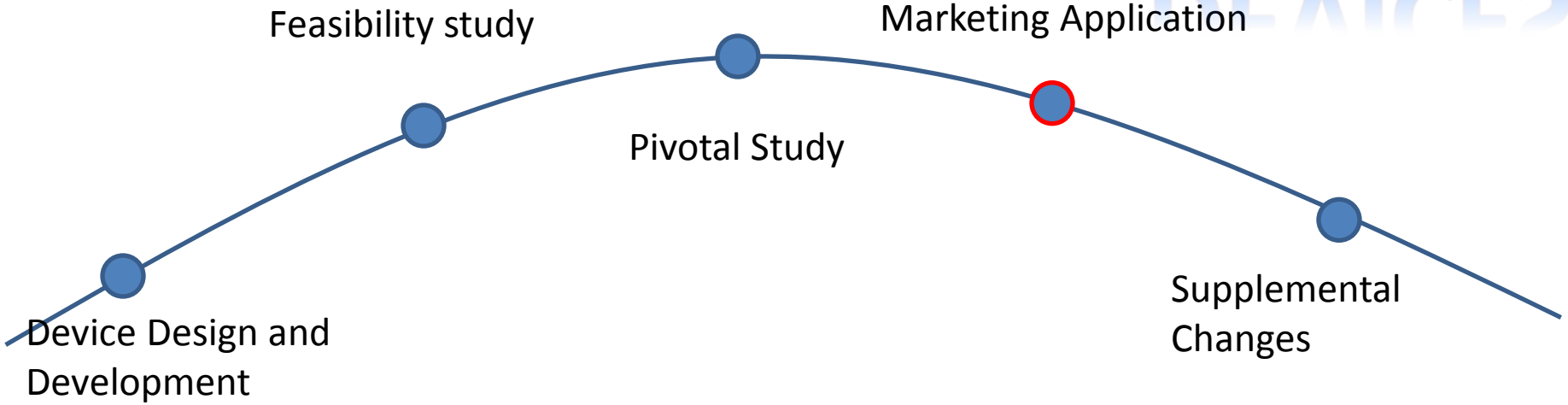
Type C Meetings Guidance

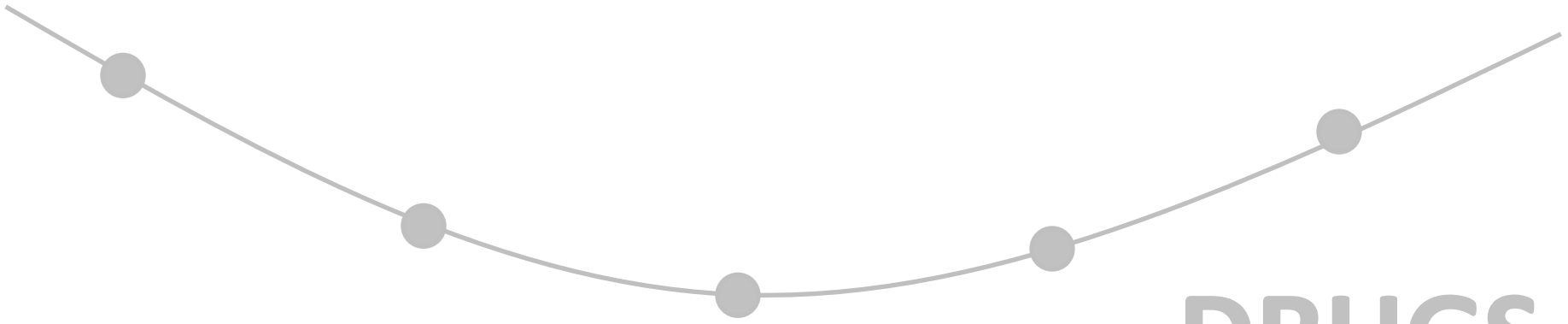
- Non Type A and Type B
- Notification of granting/denying the meeting within 21 days of receipt
- Face to Face or Teleconference
  - To be held within 75 days of the meeting request
- Written Responses only
  - Responses to be issued no later than day 60 after receipt of the request
- Briefing document to be received 1 month in advance of the meeting date (F2F or Teleconference) or goal date (WRO)

Type C Meetings

- Necessary requirements to modify the labeling to include an expanded indication
- Proposal for a planned statistical plan for a Phase 2/3 study (not under SPA)
- Regulatory pathway for the submission of an NDA/BLA
- New meeting under the PIND program
- Non-clinical testing required in support of the Phase 3 trial

DEVICES





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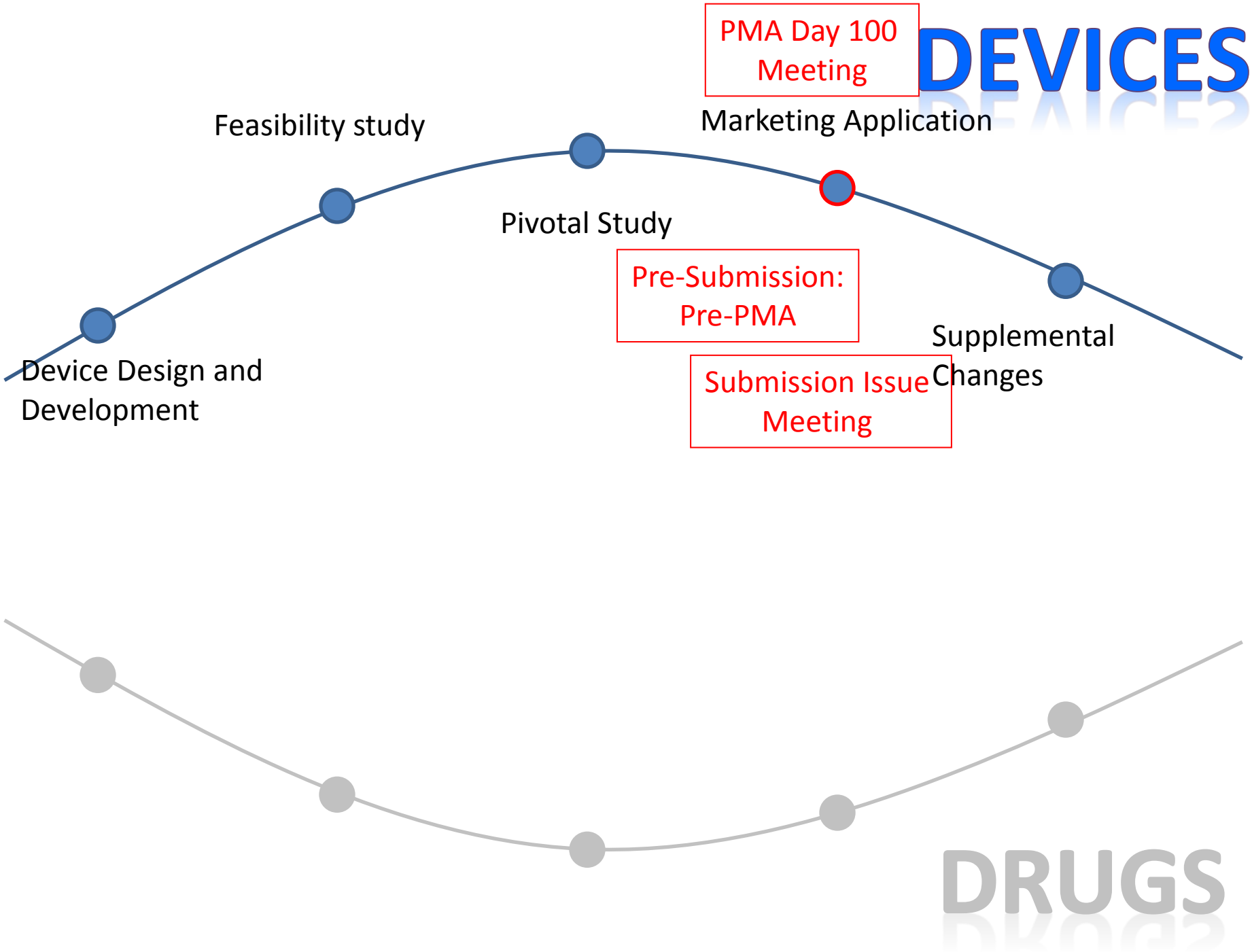
PMA Day 100 Meeting
DEVICES
Feasibility study
Marketing Application
Pivotal Study
Pre-Submission: Pre-PMA
Supplemental Changes
Device Design and Development
Submission Issue Meeting
DRUGS

Interactions at Marketing Application Stage

- **Pre-submission:** To discuss how data will be presented in the Premarket Approval (PMA) application

- **Submission Issue Meeting:** To discuss an approach to addressing a concern in the Major Deficiency Letter

- **PMA Day-100 Meeting:** To discuss the status of the PMA review. Typically requested with the PMA submission or within 70 days of filing.

Q-Submissions (Q-Subs)

Q-Submission Type	Meeting	Timeframe for Meeting/Teleconference (from receipt of submission)
Pre-Submission*	Upon request	75-90 days**
Informational Meeting	Yes	90 days
Study Risk Determination	No	N/A
Agreement Meeting	Yes	30 days or within time frame agreed to with sponsor
Determination Meeting	Yes	Scheduled within 30 days of request
Submission Issue Meeting	Yes	21 days
Day 100 Meeting	Yes	100 days (from filing of PMA)

Case study continues…

- Successfully completed Phase 3 study (ies)
- Drug product in the “to be marketed’ formulation on stability protocols
- Fast Track-rolling review
- Status of ongoing pediatric studies
- Priority review

DRUGS

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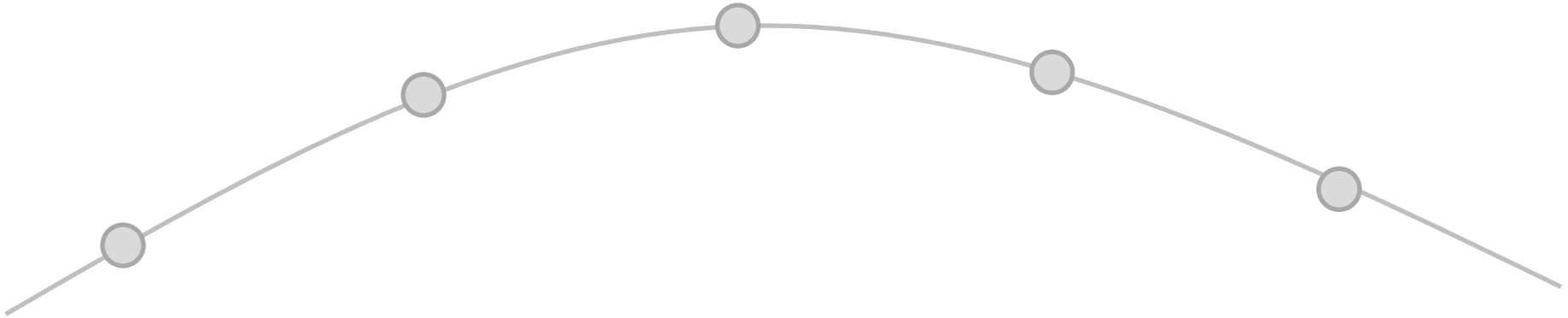
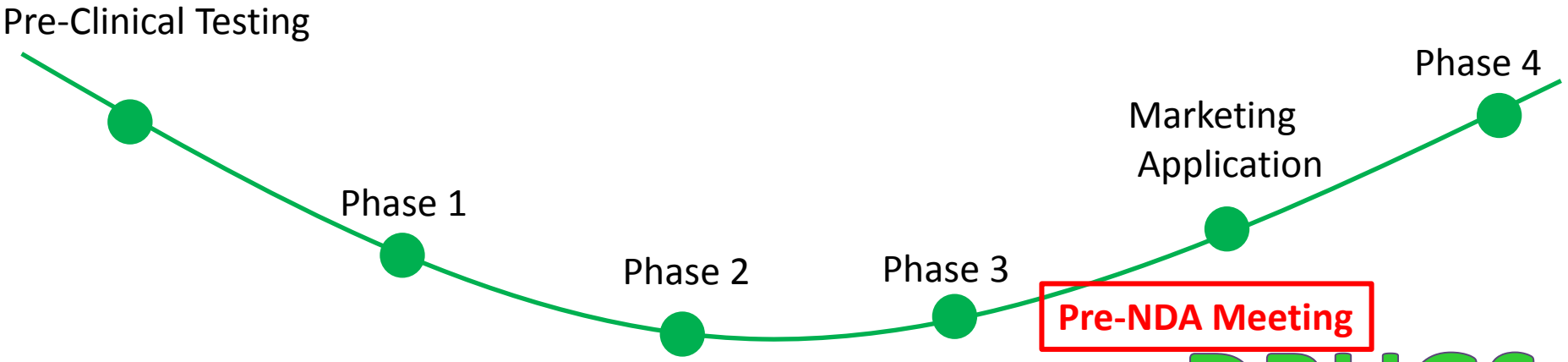




DRUGS

Pre-NDA/BLA Meeting
(21 CFR 312.47 (b)(2))

- Critical interaction between CDER staff and the sponsor in ensuring the submission of a well-organized and readily reviewable NDA/BLA

Pre NDA/BLA Meeting

Pre-Submission Meeting-PDUFA V

- To determine the adequacy of the dossier for the submission of an NDA/BLA including methods for the statistical analysis of the data
- To agree on the format and content of the application
  - eCTD, format of datasets, ISE and ISS
- To determine status of studies to address pediatric safety and effectiveness

Pre NDA/BLA Meeting

- Early discussions on priority or standard review and need for Advisory Committee
- Relevant safety information and questions/discussion points regarding proposed REMS
- REMS-Discussion on the need for post-approval risk management studies

Pre NDA/BLA Meeting

- Meeting request submitted to the file (Central Document Room)
  - Courtesy copy to the Project Manager
- Notification of granting/denying meeting within 21 days of receipt
- Face to Face (preferably) or Teleconference (if requested by applicant) scheduled within 60 days of receipt
- Briefing document to be received 1 month in advance of the meeting date

Electronic Pre-submission Meeting

- Optional
- Held 30-60 days prior to application submission
- Focus on navigation, formatting of electronic files and layout application
- Identify any technical issues prior to submission

At the conclusion of the meeting

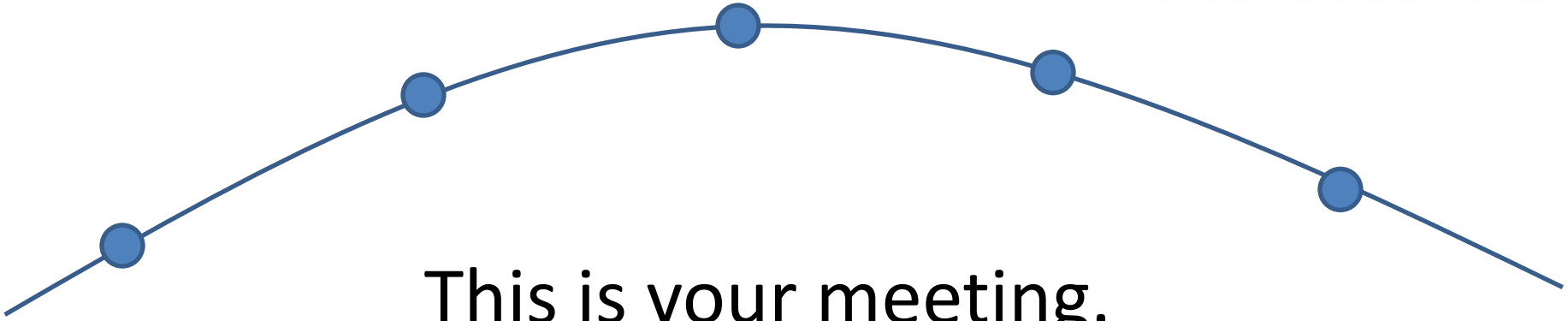
- Reached agreement on the content and format of the NDA/BLA
- Agreement on a rolling submission
- Priority will be determined once the NDA/BLA is submitted

Drug-Device Combination

- IND or IDE?
- NDA or PMA?
- Office of Combination Products
  - http://www.fda.gov/combinationproducts/default.htm
- Request for Determination (RFD)

  combination@fda.gov

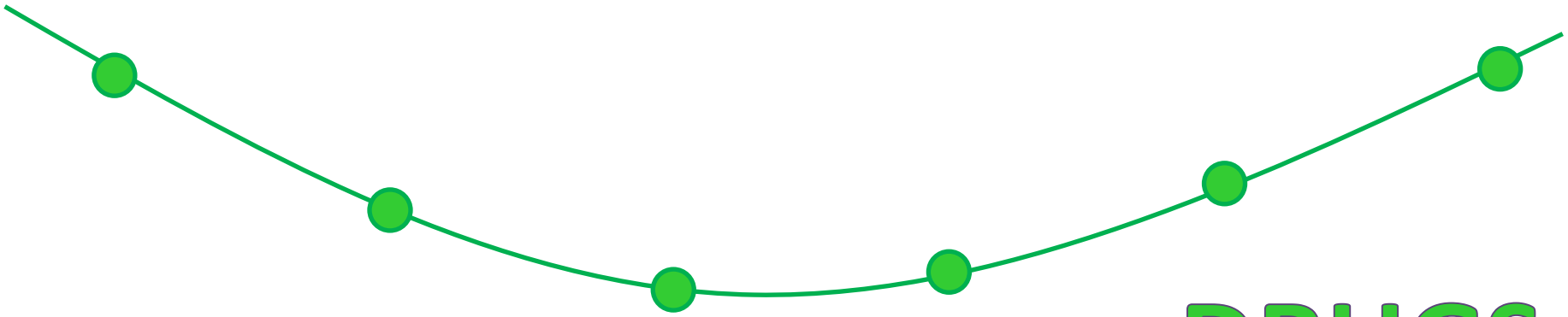
DEVICES



This is your meeting.

Use your time wisely.

Communicate clearly.



DRUGS

DEVICES

Questions?

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DRUGS

Phase 1

- Initial introduction of an investigational new drug into humans
- Small number of patients or healthy volunteers (20-80)
- Designed to determine the metabolism and pharmacologic actions, side effects associated with increased doses and if possible, to gain early evidence of effectiveness

Phase 2

- Controlled clinical studies conducted to evaluate the effectiveness of a drug, for a particular indication in patients with the disease or condition
- Determine the short-term side effects and risks associated with the drug
- Small number of patients, no more than several hundred

Phase 3

- Controlled and uncontrolled studies
- After preliminary evidence suggesting effectiveness of the drug
- Obtain information about the effectiveness and safety needed to confirm efficacy and evaluate the overall risk-benefit of the drug
- Basis of physician's labeling
- 100s-1000s patients

Phase 4

- Post Marketing
- Obtain additional information about the drug's risks, benefits, and optimal use
- May be required by the regulatory authority at the time of approval
  - Different doses or schedules of administration
  - Use of the drug in different populations, other stages of a disease or over a longer period of time

Glossary

- IND-Investigational New Drug Application
- FIH-First in Humans
- CMC-Chemistry, Manufacturing and Controls (Product Quality)
- PM, CPMS-Project Manager, Chief Project Management Staff
- PDUFA-Prescription Drug User Fee Act
- PREA-Pediatric Research Equity Act

Glossary

- NDA-New Drug Application
- BLA-Biologic License Application
- NME-New Molecular Entity
- SPA-Special Protocol Assessment
- PMR-Post Marketing Requirements
- RFD-Request for Determination
- REMS-Risk Evaluation and Mitigation Strategy