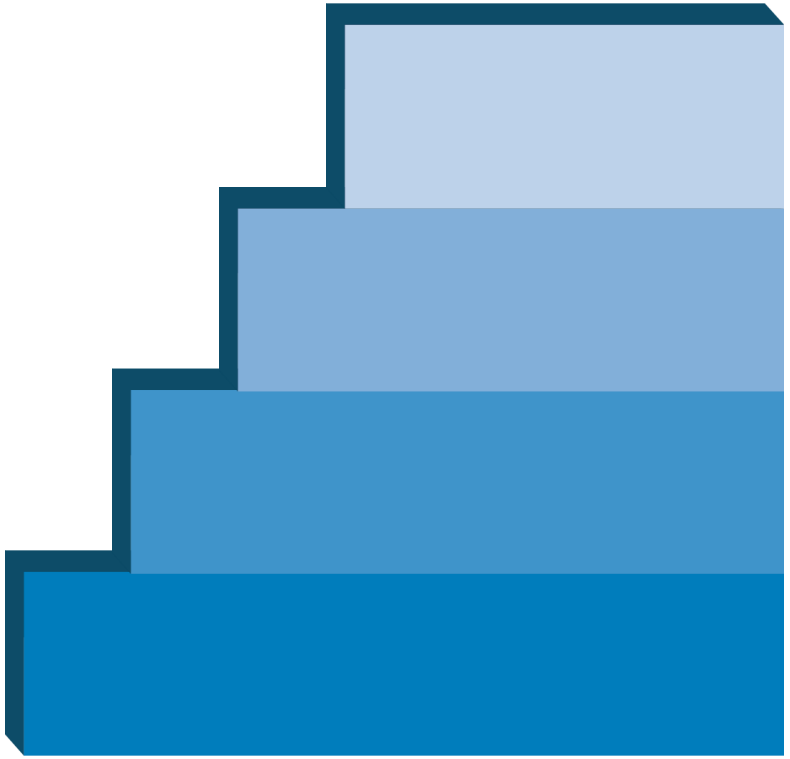
Complex Innovative Trial Designs (CID) Paired Meeting Program

The Process

FDA U.S. FOOD & DRUG ADMINISTRATION

CID Paired Meeting Program Benefits



Advancement of CID through
Trial Design Transparency

Opportunity for Collaboration

Innovative Medical Product Development

Benefit to Patients

CID Paired Meeting Program

- Five-year program (FY 2023–2027) included in the seventh iteration of the Prescription Drug User Fee Amendments (PDUFA VII)
- Joint effort of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research (CBER)
- Sponsors have the opportunity to engage with regulatory staff on CID via two meetings.
- Meetings are led by statistical review staff with participation from relevant FDA disciplines.
- FDA will select 1-2 eligible and appropriate proposals per quarter each year (i.e. up to 8 per year).

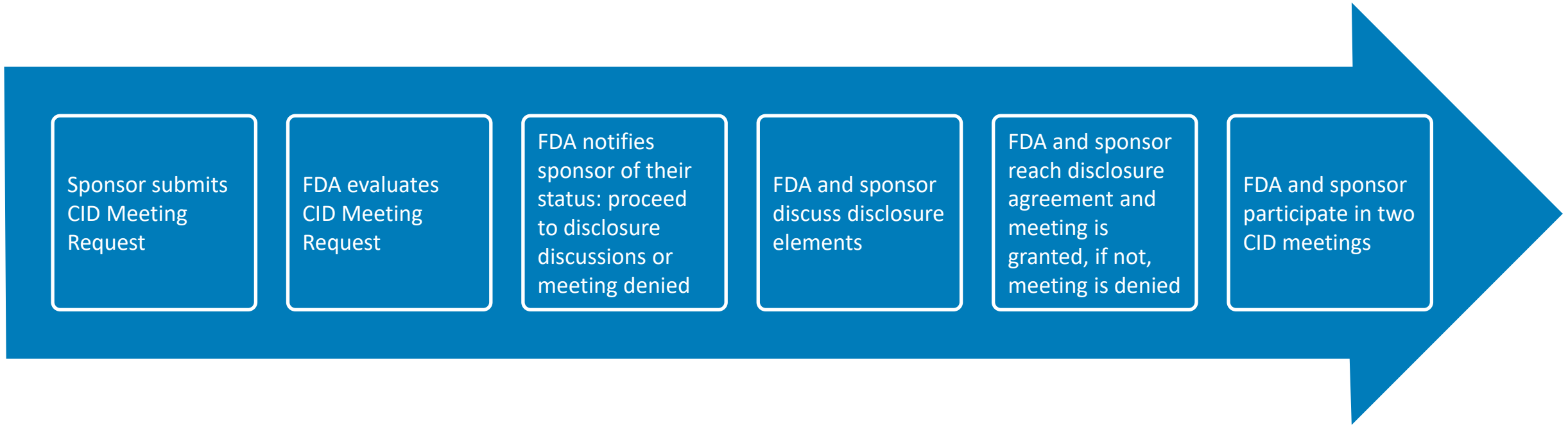
CID Paired Meeting Program

- Priority will be given to:
  - Trial designs for which analytically derived properties may not be feasible and simulations are necessary to determine operating characteristics.
  - Proposed CIDs intended to provide substantial evidence of effectiveness to support regulatory approval of the medical product.
  - Trial design features and therapeutic areas of high unmet need.

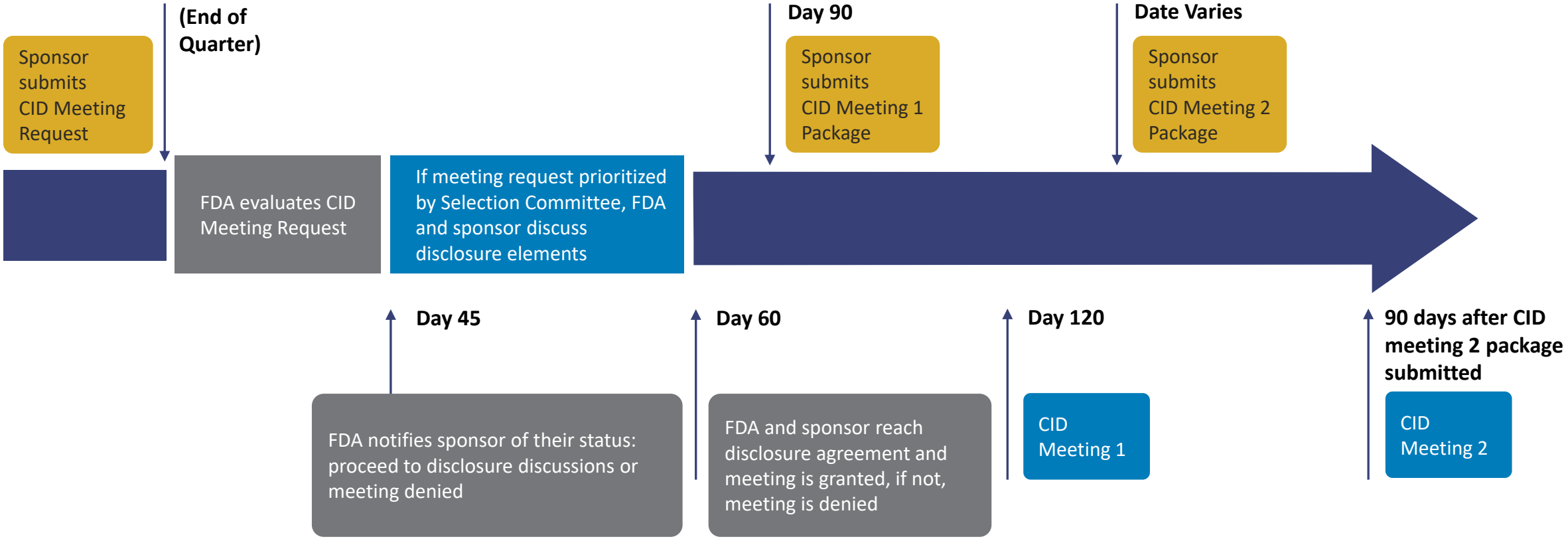
CID Paired Meeting Program Eligibility Criteria

- The sponsor must have a pre-investigational new drug (IND) application or IND number for the medical product(s) included in the CID meeting request with the intent of implementing the CID proposed in the meeting request.
- The trial is not a first-in-human study, and there is sufficient clinical information available to inform the proposed CID.
- **The sponsor and FDA are able to reach an agreement on the trial design information to be publicly disclosed.**

CID Paired Meeting Process



CID Paired Meeting Timeline



CID Paired Meeting Timeline

Sponsor Submits CID Meeting Request

CID Meeting Request contents:

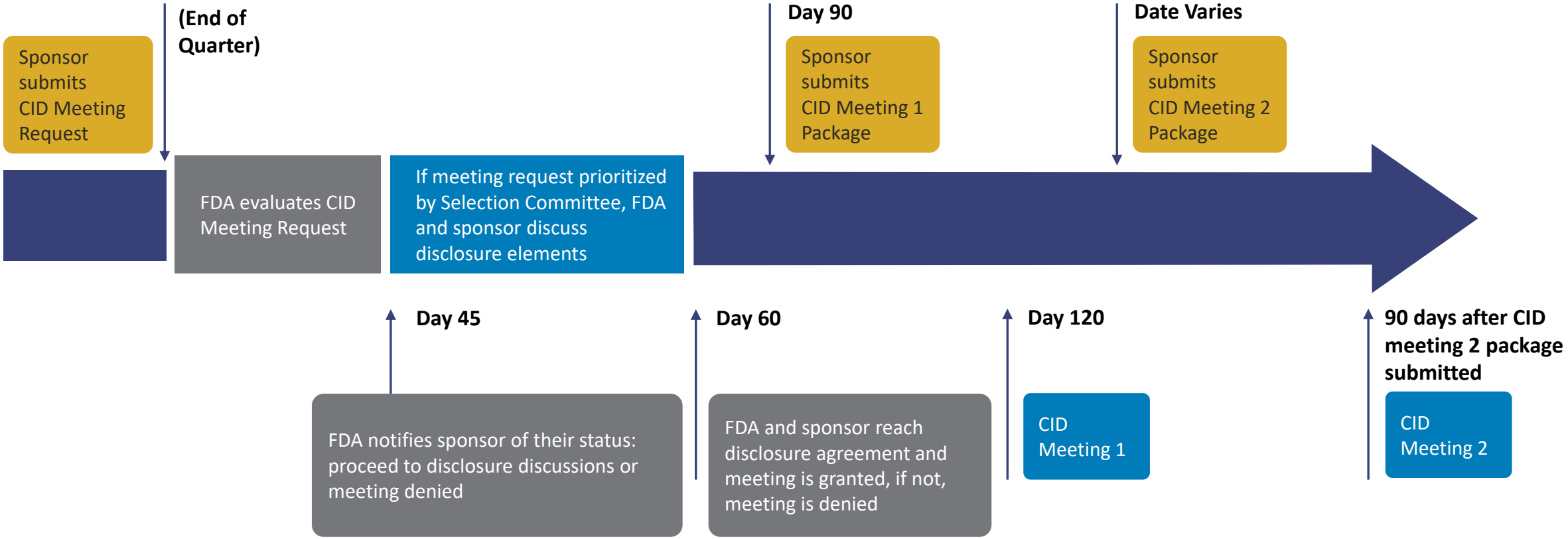
- Product name
- Application number
- Proposed indication(s) or context of product development
- A background section that includes a brief history of the development program and the status of product development
- Trial objectives
- Brief rationale for the choice of the proposed CID
- Description of study design, including study schema with treatment arms, randomization strategy, and endpoints

Sponsor Submits CID Meeting Request

CID Meeting Request contents (continued):

- Key features of the statistical analysis plan
- **Simulation plan**
- **Elements of the study design that the sponsor considers non-disclosable, along with a rationale for exclusion**
- A list of issues for discussion with the Agency about the specific proposed CID approach for the applicable drug development program

CID Paired Meeting Timeline



CID Paired Meeting Timeline

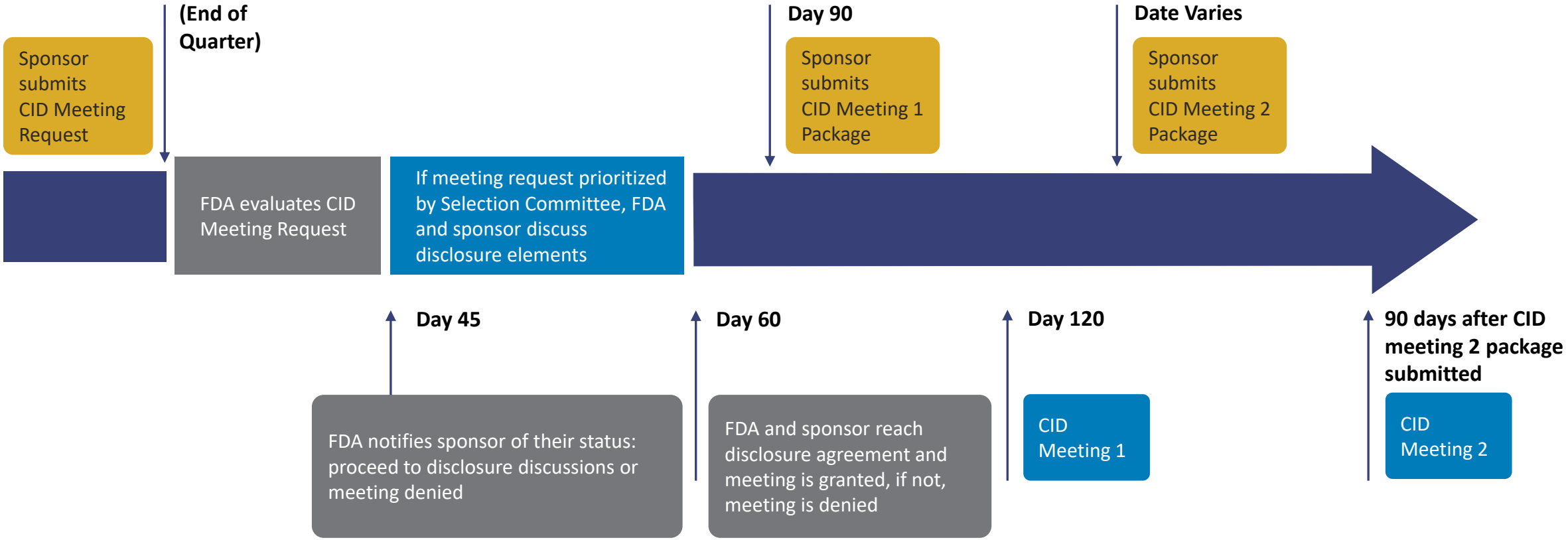
FDA evaluates CID Meeting Request

FDA Evaluates CID Meeting Request

FDA considers the following factors:

- Need for simulations to assess trial design operating characteristics
- Therapeutic need
- Level of innovation of the trial design
- Intent to provide substantial evidence of effectiveness to support regulatory approval of the medical product.

CID Paired Meeting Timeline



CID Paired Meeting Timeline

FDA and sponsor discuss disclosure elements

Day 45

FDA notifies sponsor of their status: proceed to disclosure discussions or meeting denied

Day 60

FDA and sponsor reach disclosure agreement and meeting is granted, if not, meeting is denied

FDA and Sponsor Discuss Disclosure Elements

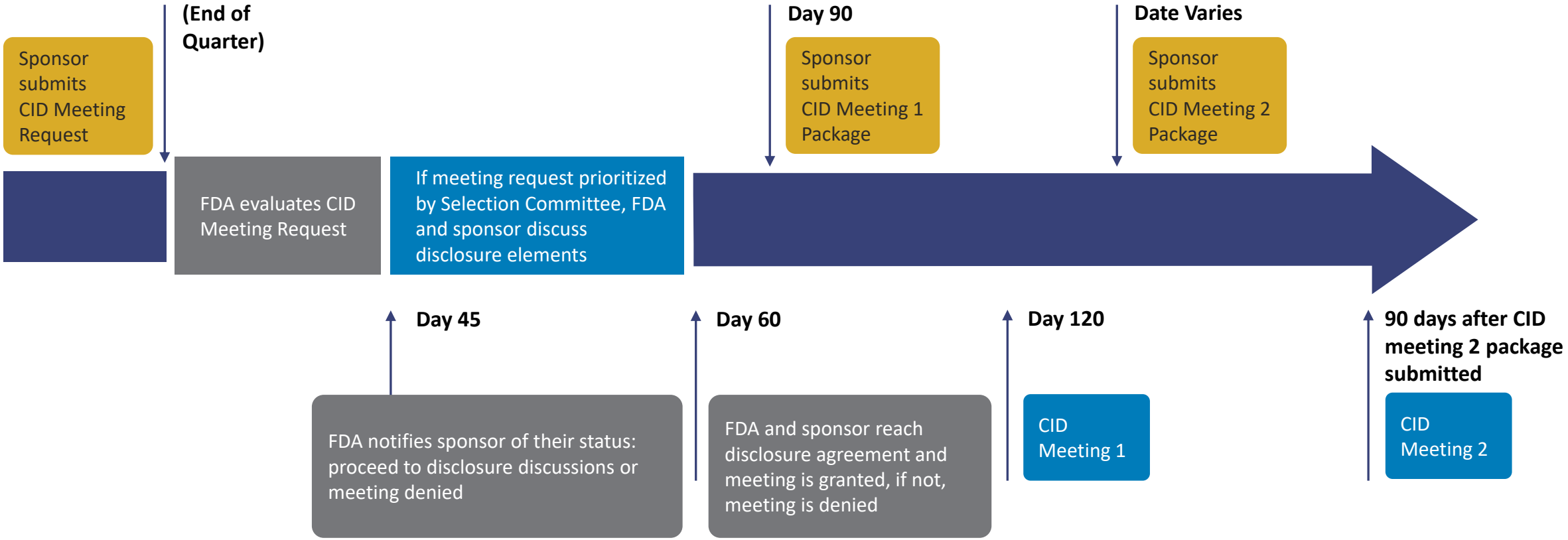
Disclosure discussion facilitates FDA and sponsor agreement regarding which elements of the study design may be disclosed.

FDA does anticipate that the following elements will generally be disclosed to facilitate discussion of the proposed CID*:

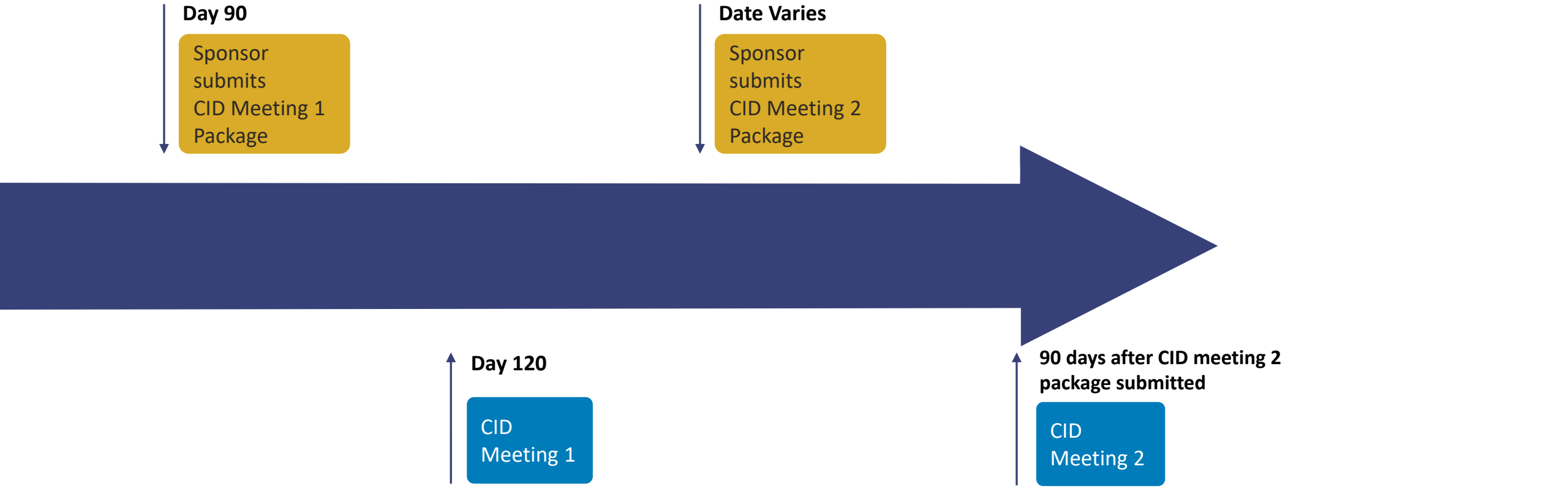
- Rationale for the selected design
- Study design characteristics
- Analysis plan
- Simulations
- Data access plan components
- Any modifications or amendments to any of the above that occur during interactions about the proposed CID between Submitter and FDA

*The CID Meeting Program *Federal Register* notice describes the elements in more detail.

CID Paired Meeting Timeline



CID Paired Meeting Timeline



FDA and Sponsor Participate in Two CID Meetings

Complex Innovative Trial Designs (CID) Paired Meeting Program
The Process

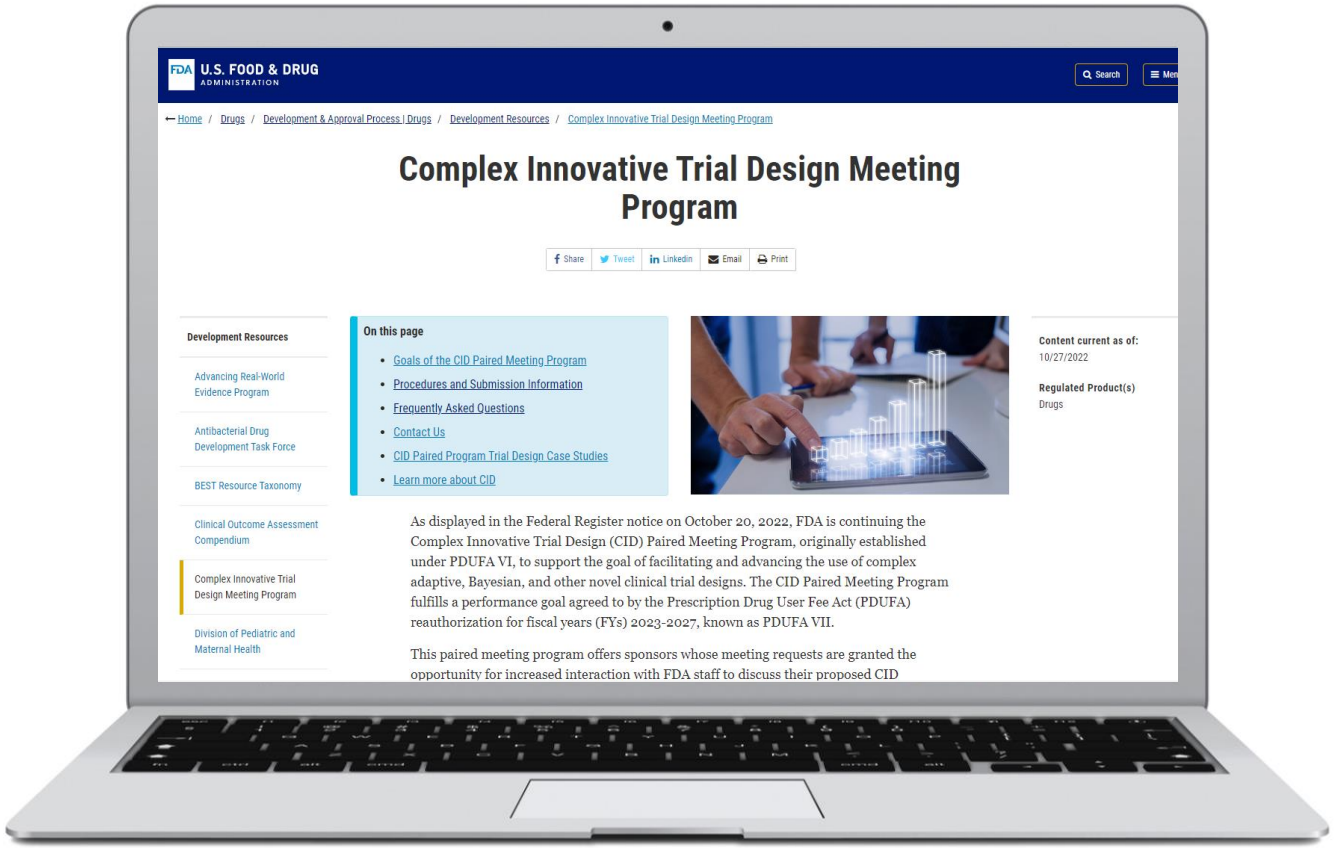
CID Meeting One Package Contents

- Product name
- Application number
- Proposed agenda, including time estimates for discussion of each agenda item
- List of questions for discussion along with a brief summary of each question that explains the need or context for the question
- Detailed description of the statistical methodology
- **Detailed simulation report***
- **Overall conclusions, including:**
  - **A brief summary of the simulated operating characteristics, based on design features and analyses**
  - **A discussion of the utility of the CID, given the simulation results**

*The CID Meeting Program *Federal Register* notice describes the required components of the simulation plan.

CID Meeting Two Package Contents

- Product name
- Application number
- Updated background section that includes a brief history of the development program and the status of product development and clinical data to date, if applicable
- Proposed agenda, including estimated times needed for discussion of each agenda item
- List of questions for discussion along with a brief summary of each question that explains the need or context for the question
- **Updated programs/shells for simulations, if applicable**
- Summary of new information that is available to support discussions



Complex Innovative Trial Designs (CID) Paired Meeting Program
The Process

CID Paired Meeting Program Success

Advances the use of complex adaptive, Bayesian and other novel clinical trial designs

CID Paired Meeting Program Success

Patients Benefit

Promotes development of new therapies across a diverse range of therapeutic areas where the need exists

Thank you!

For more information, visit www.fda.gov/CID

For questions, please email CID.Meetings@fda.hhs.gov