PROXIMA
CLINICAL RESEARCH

Breakthrough Device Designation

greenlight guru

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

114k
look to us for the latest in quality

FEATURED IN

THE WALL STREET JOURNAL.
THE VERGE
TechCrunch
Forbes
QUALITYDIGEST
MDDI
Inc.
MedTech Intelligence
MED DEVICE ONLINE
Medical Design & OUTSOURCING
TNW THE NEXT WEB
Entrepreneur
MPO

"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

greenlight guru

PROXIMA
CLINICAL RESEARCH

You have an innovative medical device or drug, and you need an organization experienced in getting products approved and on the market.

We know your needs. We know the pitfalls of the submission process and how to avoid them.

From regulatory consulting to clinical research, Proxima is the dedicated full-service Contract Research Organization for emerging companies.

What We'll Talk About Today

1. Basics on Designations
2. Eligibility Criteria
3. Timelines
4. Submission Style
5. Benefits
6. Tips & Tricks Throughout

WHAT IS THE BREAKTHROUGH DEVICES PROGRAM?

Voluntary, expedited device approval program for certain devices and combination products that provide more effective treatment or diagnosis of life-threatening diseases or conditions.

BENEFITS INCLUDE:

Prioritized Review

Interaction with FDA

BREAKTHROUGH DESIGNATION

Eligibility

IS MY DEVICE ELIGIBLE FOR A BDD?

CRITERION 0

Device must be subject to the PMA, 510(k), or De Novo pathways

CRITERION 1

The device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.

CRITERION 2

- **A** Represents Breakthrough Technology
- **B** No approved or cleared alternatives exist
- **C** Offers significant advantages over existing approved or cleared alternatives
- **D** Device availability is in the best interest of patients

CRITERION 1: The device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions

- "More effective", Complete set of clinical data is not required

- Reasonable expectation of technical success & clinical success

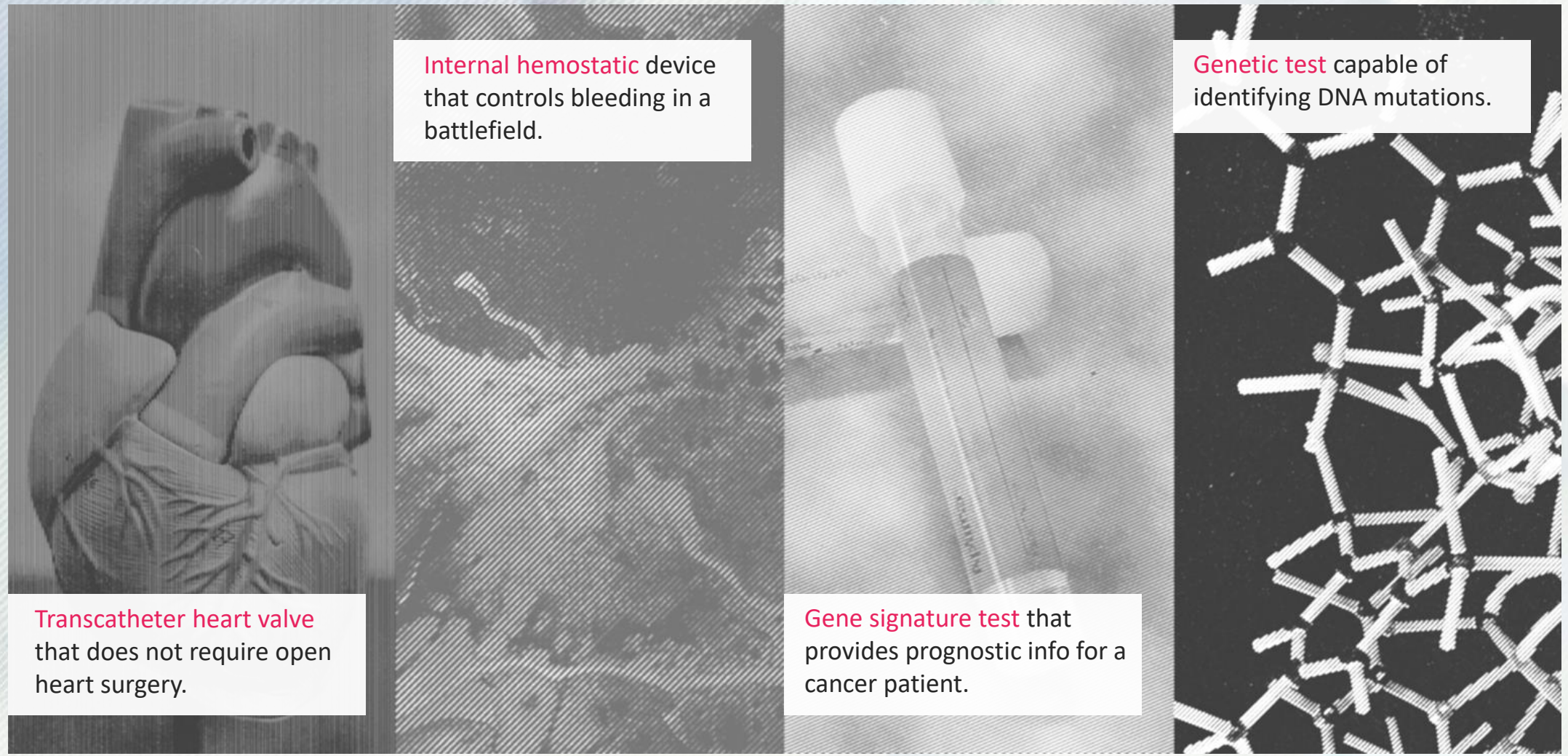
- "Life-threatening", the likelihood of death is high

- "Irreversibly debilitating", impacts day-to-day functioning

CRITERION 2A: Device Represents Breakthrough Technology

- Does it represent a novel technology or novel application of an existing technology?
- Does it have the potential to lead to a clinical improvement in the diagnosis, treatment, cure, mitigation, or prevention of the life-threatening or irreversibly disease or condition?

EXAMPLES OF TECHNOLOGIES THAT MEET CRITERION 2A



Transcatheter heart valve that does not require open heart surgery.

Internal hemostatic device that controls bleeding in a battlefield.

Gene signature test that provides prognostic info for a cancer patient.

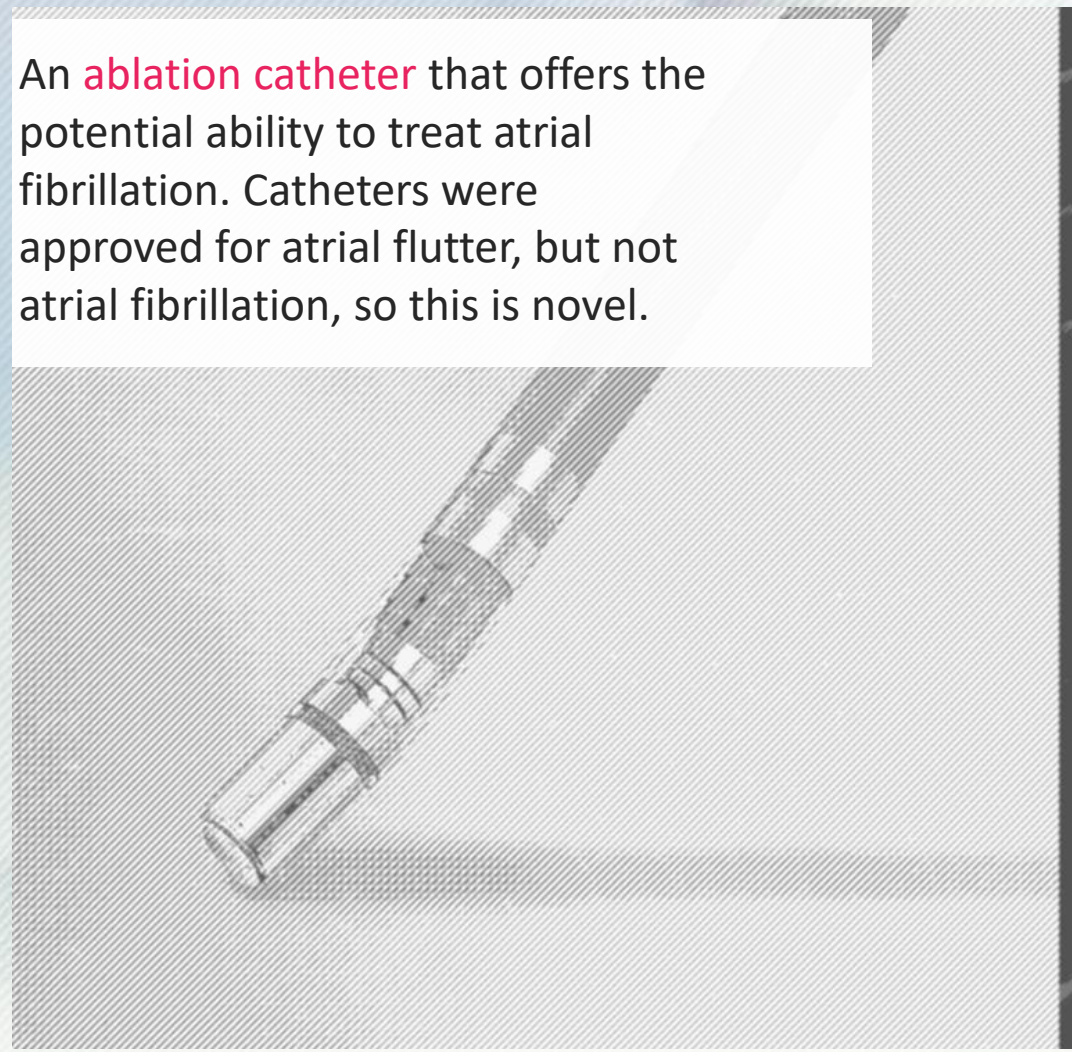
Genetic test capable of identifying DNA mutations.

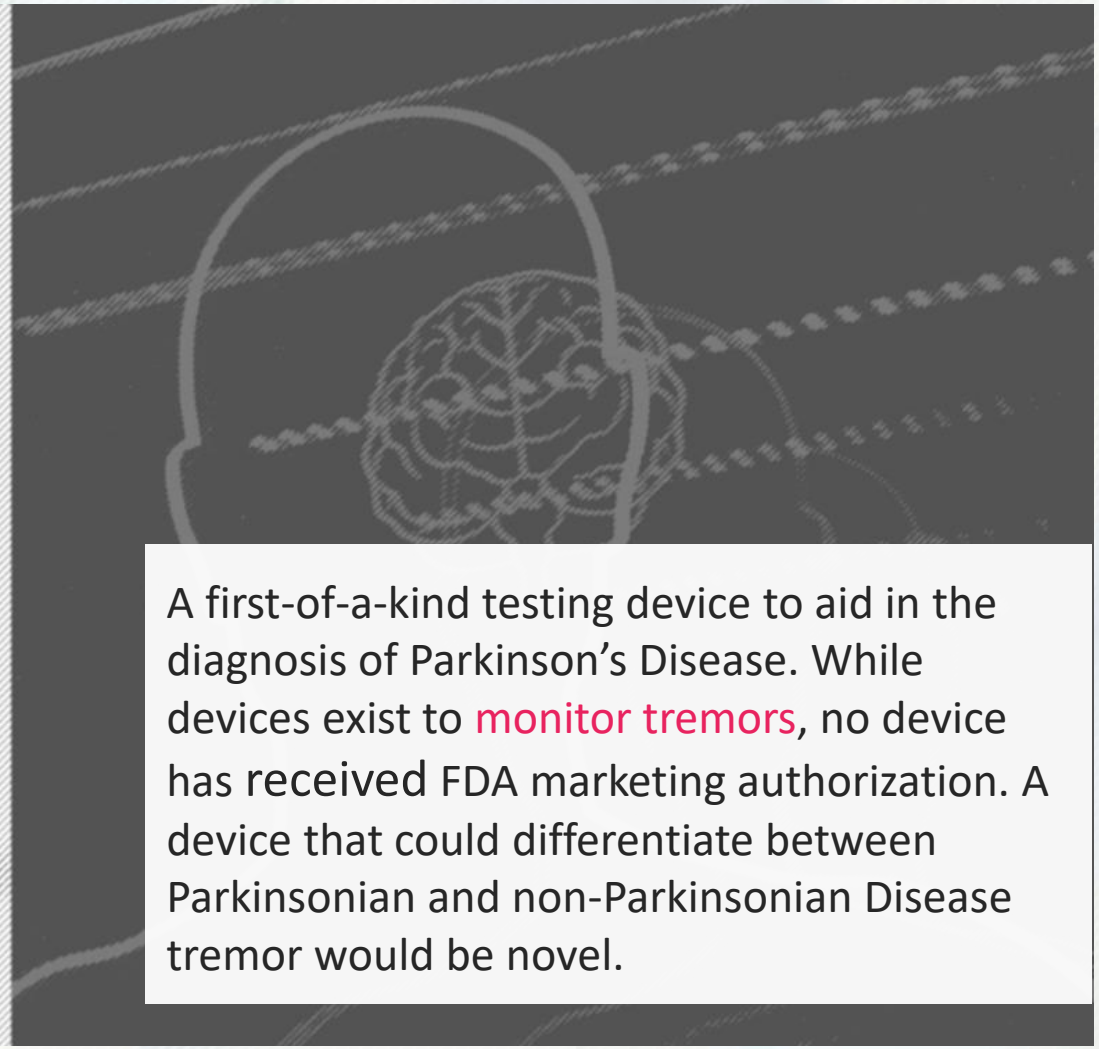
CRITERION 2B: No Approved or Cleared Alternatives

- Received FDA market authorization for the same indication being considered.
- Consistent with the current US standard of care.

EXAMPLES OF TECHNOLOGIES THAT MEET CRITERION 2B

An ablation catheter that offers the potential ability to treat atrial fibrillation. Catheters were approved for atrial flutter, but not atrial fibrillation, so this is novel.



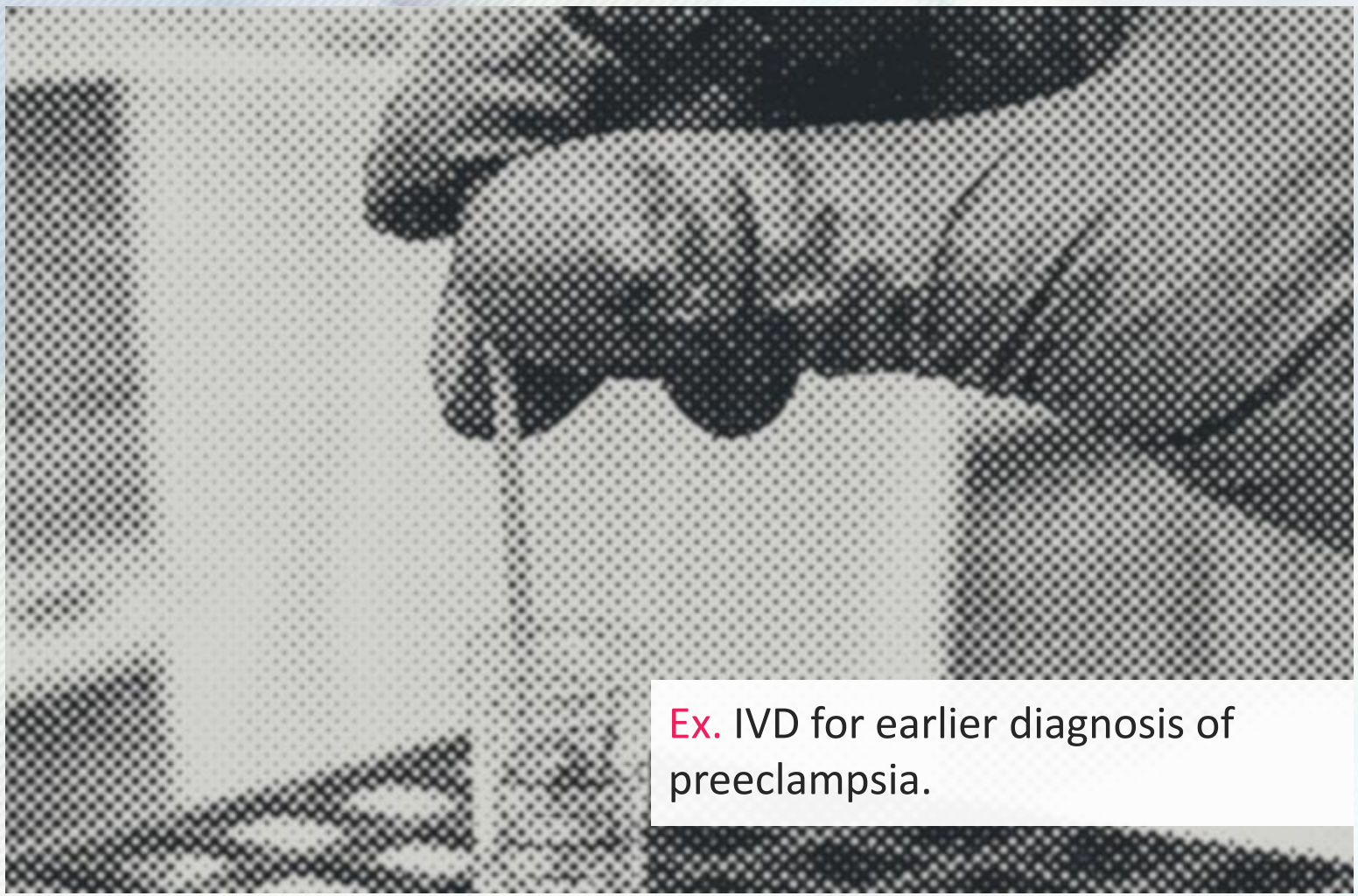


A first-of-a-kind testing device to aid in the diagnosis of Parkinson's Disease. While devices exist to monitor tremors, no device has received FDA marketing authorization. A device that could differentiate between Parkinsonian and non-Parkinsonian Disease tremor would be novel.

CRITERION 2C: Device Offers Significant Advantages over Existing Approved or Cleared Alternatives

- Reduce or eliminate the need for hospitalization
- Improve patient quality of life
- Facilitate patients' ability to manage their own care
- Establish long-term clinical efficiencies

EXAMPLES OF TECHNOLOGIES THAT MEET CRITERION 2C



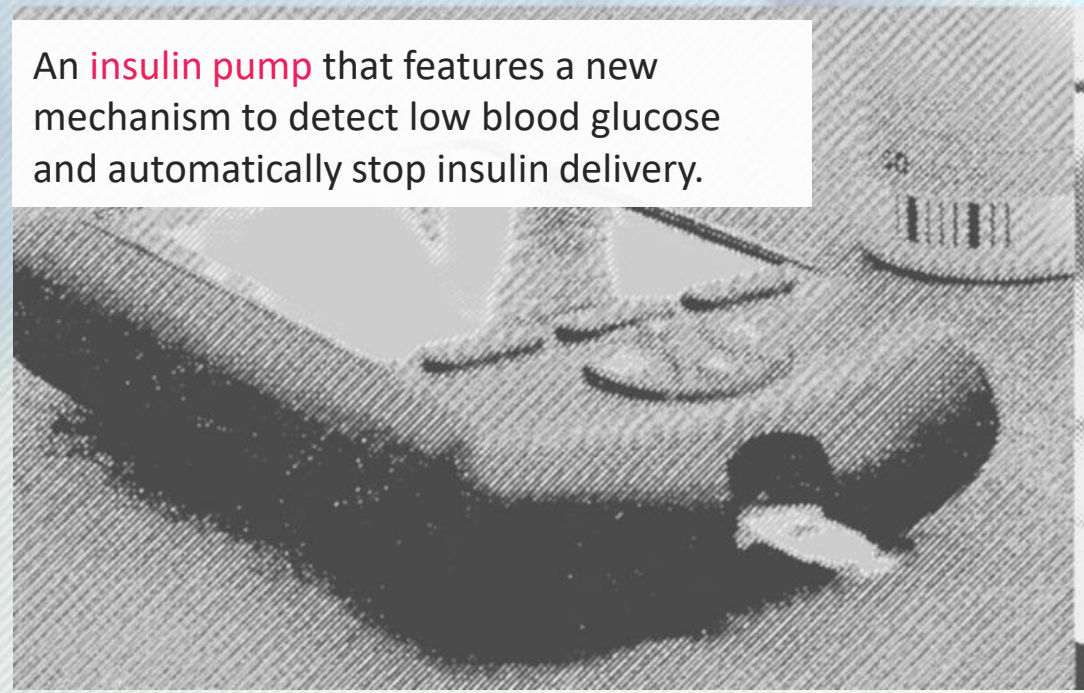
Ex. IVD for earlier diagnosis of preeclampsia.

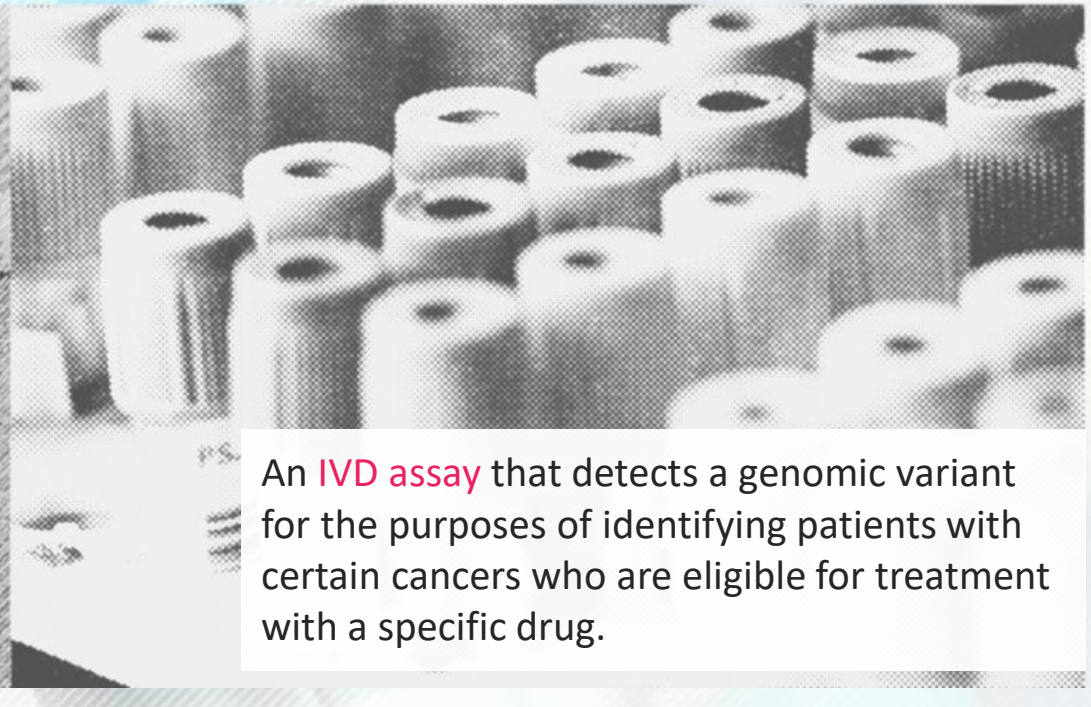
CRITERION 2D: Device availability is in the best interest of patients

- Better care and patient outcomes from a public health perspective
- Benefit patients who are unable to tolerate available therapy or did not respond to alternative therapies
- Avoid harm that could result in discontinuation of treatments
- Provide improved patient compliance

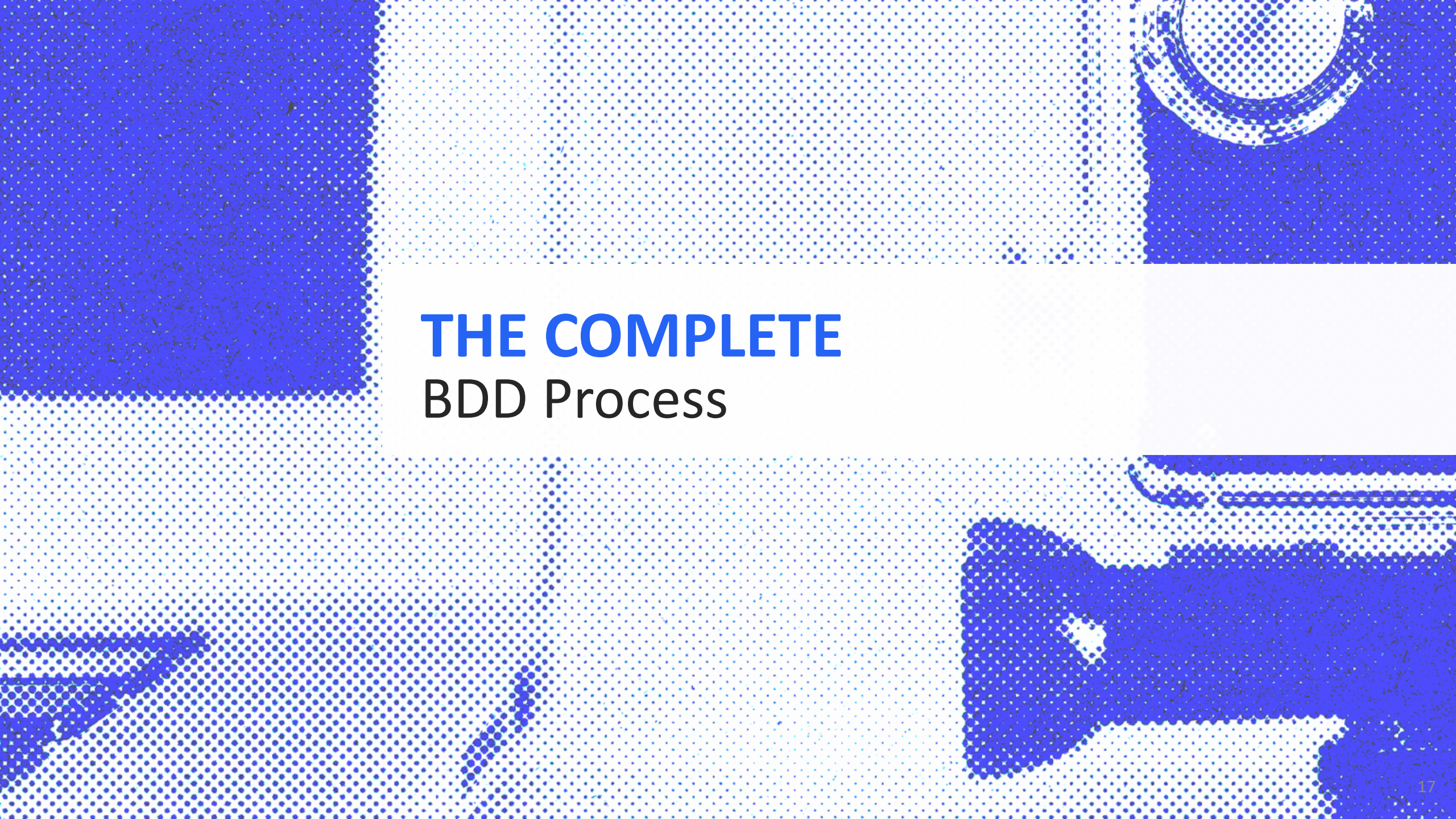
EXAMPLES OF TECHNOLOGIES THAT MEET CRITERION 2.4

An insulin pump that features a new mechanism to detect low blood glucose and automatically stop insulin delivery.





An IVD assay that detects a genomic variant for the purposes of identifying patients with certain cancers who are eligible for treatment with a specific drug.


THE COMPLETE
BDD Process

REQUESTING A BDD

When?

Prior to submitting a PMA, 510(k), or De Novo request

How?

Submit a “Designation Request for Breakthrough Device” Q-Sub.

Include:

- ❑ Device description
- ❑ Proposed indication for use
- ❑ Regulatory history
- ❑ How the device meets the designation criteria
- ❑ Type of marketing submission for the device

ADDITIONAL CONSIDERATIONS:

- Regulatory Path
  - Submission of PMA, 510(k) or De Novo is necessary for marketing authorization
- Multiple Devices with Same Intended Use
  - BDD can be granted for multiple devices with the same intended use if pending simultaneously
  - When a BDD device has been approved or De Novo request is granted, no other devices can receive a BDD
- Combination Products
  - More difficult for combination products to receive BDD

DESIGNATION REVIEW

- The designation request should be the only request contained in the Q-Submission
- Within 30 days of submission, the FDA will interact with the sponsor regarding any requests for additional information needed to inform the designation decision
- Within 60 days of submission, the FDA will issue a grant or denial decision

DESIGNATION WITHDRAW

- A sponsor may withdraw from the program at any time
- FDA will not withdraw if another device with the same intended use received approval through PMA, 510(k), or De Novo
- FDA will withdraw designation if:
  - The device is no longer eligible for a BDD
  - The information submitted in support contained an untrue statement or omitted information

WHY REQUEST A BDD?

Interactive communication

Flexibility with clinical studies

Quality management

Higher priority

Dedicated, available, and well-trained review teams

THE COMPLETE

STeP Process

IS MY DEVICE ELIGIBLE FOR STeP?

CRITERION 1

Not eligible for the Breakthrough Devices Program due to the less serious nature of the disease or condition treated, diagnosed, or prevented by the device

CRITERION 2

Should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for at least one of the following:

A. A reduction in the occurrence of a known serious adverse event

B. A reduction in the occurrence of a known device failure mode

C. A reduction in the occurrence of a known use-related hazard or use error

D. An improvement in the safety of another device or intervention

CRITERION 1: Not treating or diagnosing life-threatening or irreversibly debilitating disease

What kind of conditions?

- Negatively impact quality of life for short time frame
- Be debilitating for short time frame
- Might not significant impact daily function
- Might not worsen

CRITERION 2A: A reduction in the occurrence of a known serious adverse event

- Lead to development of life-threatening conditions, disability or permanent damage, or subsequent treatment or intervention to prevent permanent impairment or damage
- Occur in acute timeframes following treatment or diagnosis or long term adverse outcomes
- Change in principles of operation

CRITERION 2B: Reduction in the occurrence of a known device failure mode

- Based on analysis of MAUDE, MedSun, Recalls, Literature
- Based on risk analysis of your device
- Not hypothetical

CRITERION 2C: A reduction of a known use-related hazard or error

- Not component failure, materials, or technological risk
- Changes to device design or operational features

CRITERION 2D: An improvement in the safety of another device or intervention

- May be an accessory to another device
- Reduce the risk associated with a procedure (e.g., less invasive)

SUBMITTING A STeP REQUEST

When?

Prior to submitting a PMA, 510(k), or De Novo request

How?

Submit a “Request for Inclusion in STeP” Q-Sub.

Include:

- ❑ Device description
- ❑ Proposed indication for use
- ❑ Expected safety improvement
- ❑ Regulatory history
- ❑ How the device meets the STeP objectives
- ❑ Type of marketing submission for the device

DESIGNATION REVIEW

- The designation request should be the only request contained in the Q-Submission
- Within 30 days of submission, the FDA will interact with the sponsor regarding any requests for additional information needed to inform the designation decision
- Within 60 days of submission, the FDA will issue a grant or denial decision

DESIGNATION WITHDRAW

- A sponsor may withdraw from the program at any time
- FDA will not withdraw if another device with the same intended use received approval through PMA, 510(k), or De Novo
- FDA will withdraw designation if:
  - The device is no longer eligible for STeP
  - The information submitted in support contained an untrue statement or omitted information

SUBMISSION STYLE

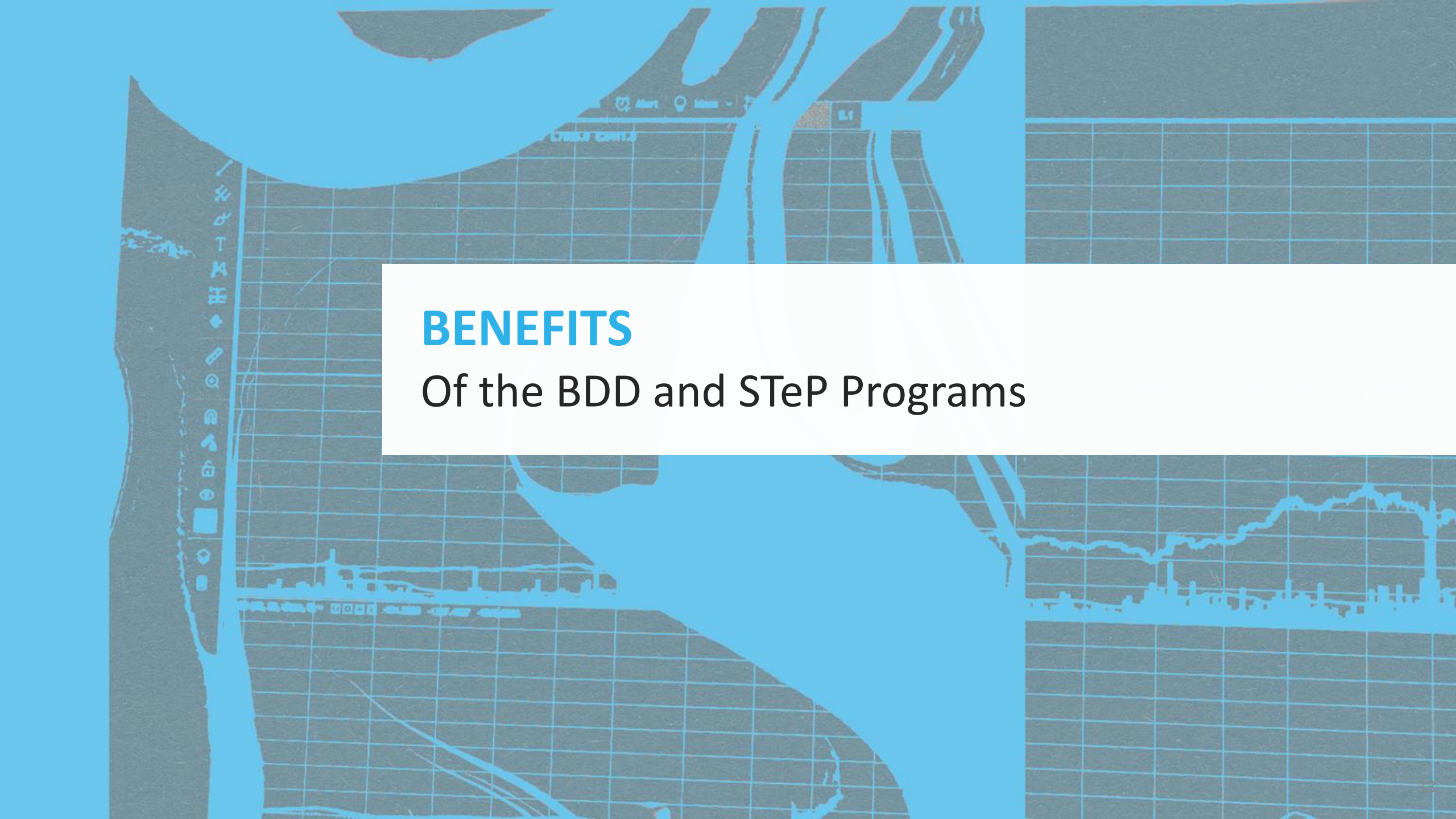
Of the BDD and STeP Programs

SUBMISSION STYLE

Submission Style

- No required format
- Recommended to tell it like a story
  - Exposition: Background
  - Protagonist: Device
  - Conflict: Problem with SOC
  - Resolution: Device saves the day!
- More thesis and argument driven than other submission types

For criterion, set stage with problem, then introduce device as solution, then provide evidence as to how.



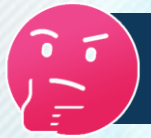
BENEFITS

Of the BDD and STeP Programs

WHAT IS A SPRINT DISCUSSION?

Sprint discussions are used to help the FDA and sponsors reach mutual agreement on a specific topic within a set time period (i.e. 45 days).

The FDA also offers opportunities through the Data Development Plan (DDP) and clinical protocol agreement.



Things to consider:

1. Single topic with specific goals
2. Interaction schedule, planned participants
3. Documentation of interactions & conclusions
4. Available supporting materials

EXAMPLE SPRINT DISCUSSION TIMELINE

DAYS

1	7	14	21	28	35	40	45
Submission	Informational discussion to walk through FDA through materials and questions.	FDA emails initial feedback	Discuss initial feedback and questions	Sponsor provides additional info	Teleconference meeting, discuss disagreements	Sponsor emails draft minutes	FDA provides edits to meeting minutes

MARKETING OPPORTUNITIES AND INVESTOR INTEREST

Another perk is the ability to provide more opportunities for marketing and securing investor funds.

With direct attention from the FDA, the added appeal to investors means untapped market potential and less risk going through the regulatory process.

Things to consider:

1. Highlight key areas of use that support the overall value proposition for the product

2. Requires stakeholders to educate themselves to fully understand the benefits of their devices and the program in order to submit successfully

REIMBURSEMENT AWARDS

With eligibility for the New Technology Add-On Payment (NTAP) pathway, CMS is aware that there won't be enough time to demonstrate clinical improvement.

Certain cases that have high costs when involving eligible new medical technologies will be met with a finalized add-on payment that is equal to the lesser than 65% of the cost of the new service or breakthrough device.

This lends opportunity to potential reimbursement.

Things to consider:

1. Devices must still meet cost criteria
2. NTAP does not necessarily guarantee reimbursement as additional factors are to be considered when discussing coverage

CONTACT

ISABELLA SCHMITT
Isabella@ProximaCRO.com