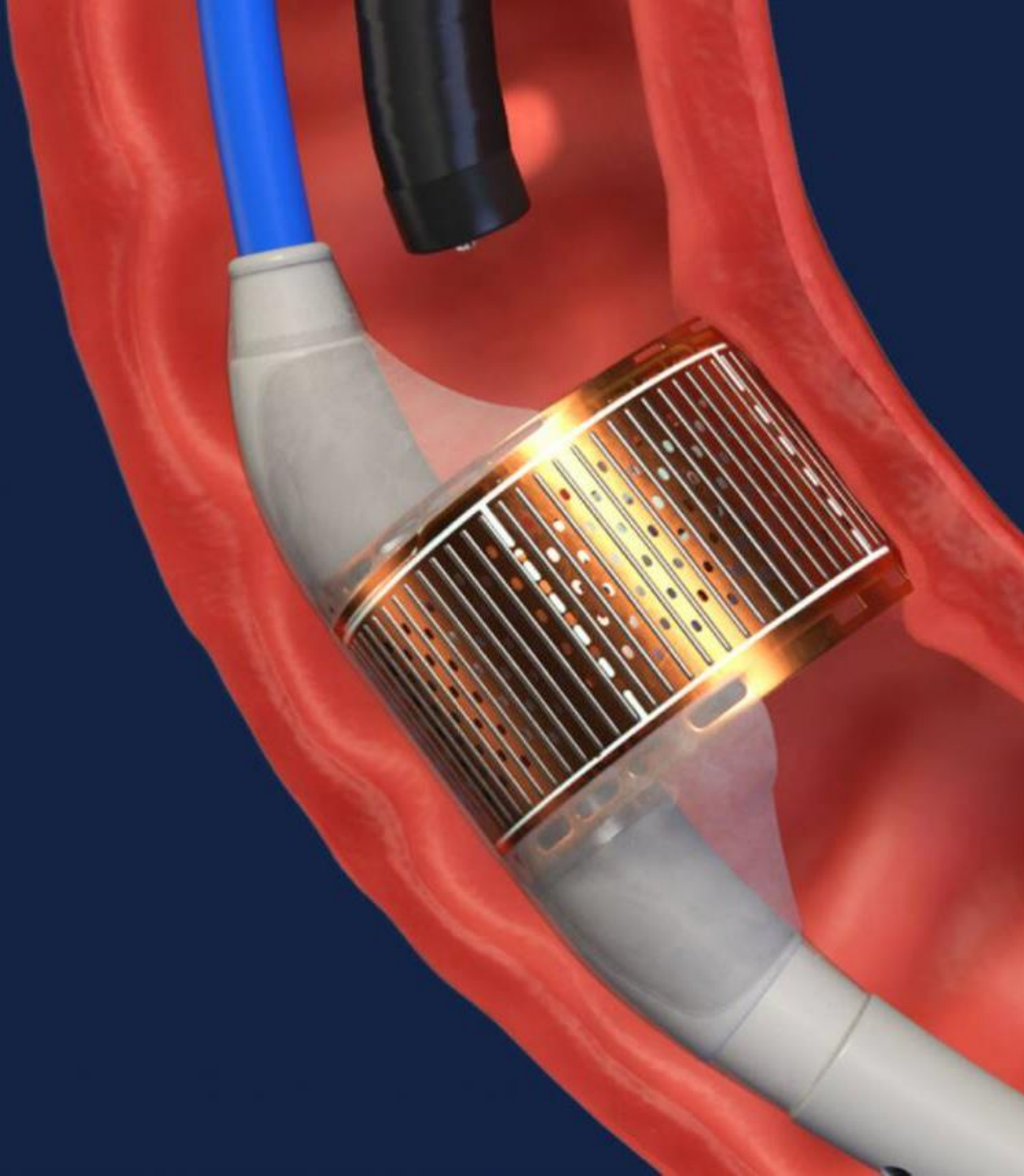# Building a Robust Medical Device Clinical Development Program: Best Practices and Insights

Lian Cunningham, M.D., Ph.D

Vice President of Clinical Affairs

Endogenex Inc.

17th Annual Outsourcing in Clinical Trials West Coast 2025
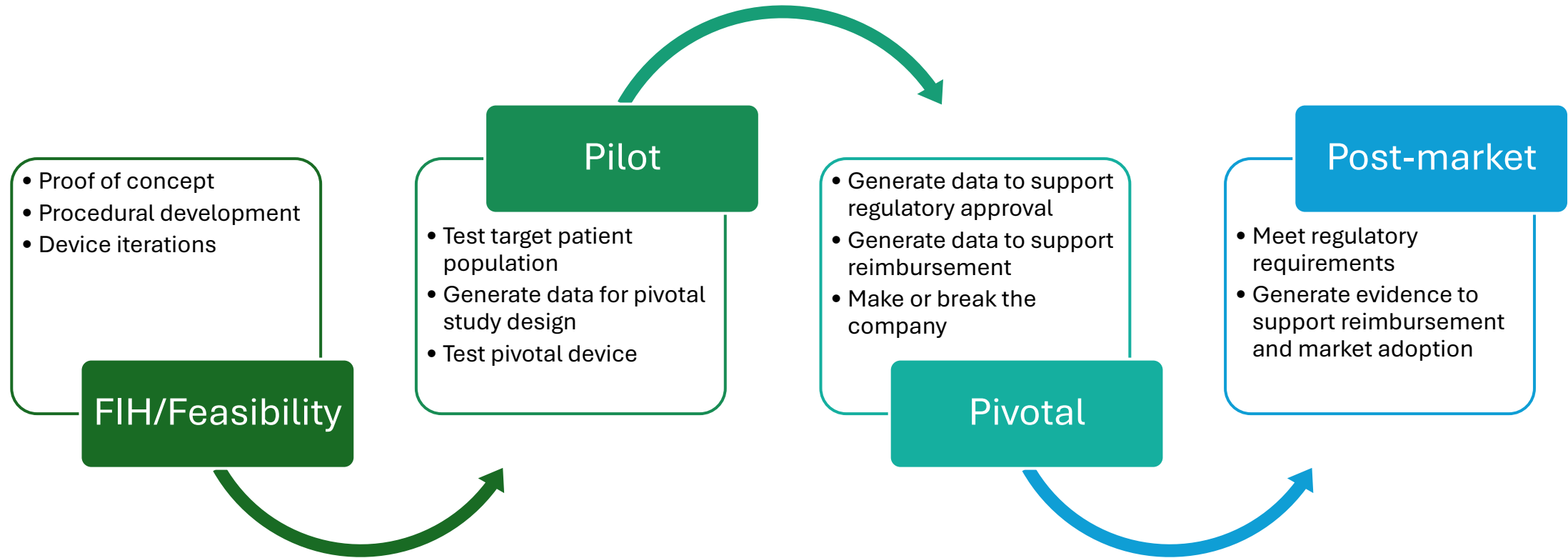
Endogenex™

Endoscopic duodenal recellularization via electroporation for treatment of type 2 diabetes

- ➤ Noval technology, Class III device
- ➤ Feasibility studies completed
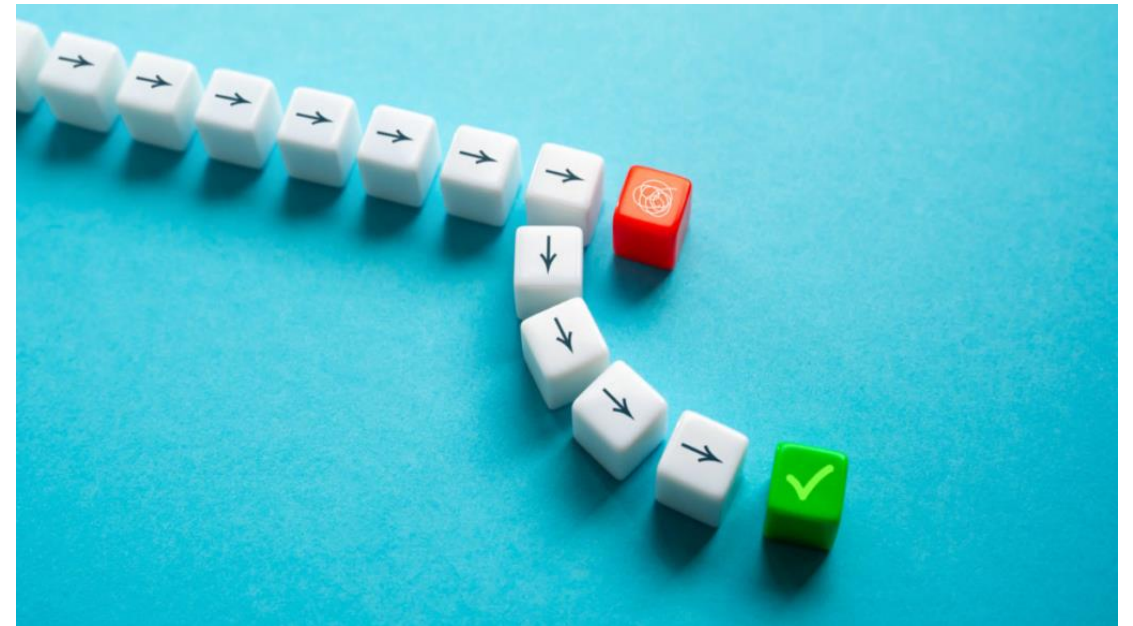- ➤ ReCET pivotal study is enrolling

Topics

➢Key considerations for medical device clinical development program at different stages

➢Optimize protocol design using data-driven approaches

➢Leveraging policy advantages of Asia-Pacific to accelerate the program timeline

➢Important factors when selecting a contract research organization (CRO) or other partners to manage a successful medical device study

Medical Device Clinical Development Program

Key Considerations ---Feasibility Phase

- Focus on technical learning and safety
  - Investigator technical skills
  - Local standard of care

- Anticipate changes
  - Device iterations
  - Protocol amendment
  - Finance

- Plan and enable changes
  - Protocol design
  - Geography and regulatory process

Select Geography for Feasibility Studies

Regulatory clarity

Streamlined process

Predictable timeline

High-quality research sites

Investigator technical skills

Representative patient population

Standard of care

Marketing considerations

A Case Study – a feasibility study in Australia, why?

- Australia conforms to global standards (ICH, ISO14155)

- HREC approval → TGA notification

- National CTA template

- Timeline transparent and predictable

- High-quality research sites

- Data acceptance by FDA

- Cotemporary standard of care

- Representative patient population

- R&D Tax Incentive

CRO Selection for Feasibility Phases

- Local regulatory expertise

- Local relationship with sites

- Device experience

- FIH study experience

- Therapeutic area experience

- Flexible, can manage changes

Local, Small, Nimble, and…… a Good Fit.

Pilot Phase

- Bridge between feasibility and pivotal

- When is a pilot study needed prior to the pivotal study?

  - Changes in patient population that may impact efficacy or safety

  - Changes in standard of care

  - Modifications to the device

  - Insufficient data for sample size estimation

But sometimes we have to take a leap......

Key Considerations ---Pivotal Phase

- Define business objectives
  - Regulatory approval(s)
  - Reimbursement
  - Market adoption

  > - Involve key stakeholders
  > - Be realistic

- Develop protocol internally
  - Consult with medical advisors, investigators, statistician, and CRO
- Take advantage of CRO expertise, infrastructure, and resource capacity for trial execution
- Maintain control of site selection
- Maintain control of project execution
- Ensure technical support
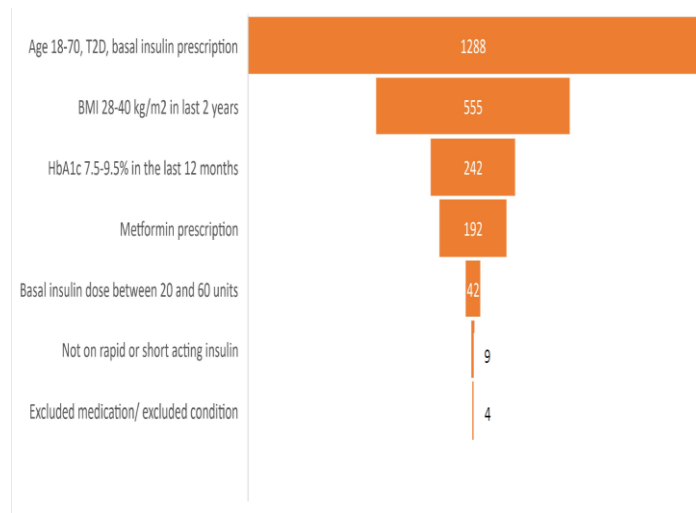
CRO Selection for Pivotal Phase

CRO Screen 〉 RFP 〉 Bid Defense 〉 Contract

✓ Device trial experience

✓ Experience in similar trial design

✓ Therapeutic area, indication

✓ Complementary expertise

✓ Functions and resources for the scope of the project

✓ Compatibility (size, culture)
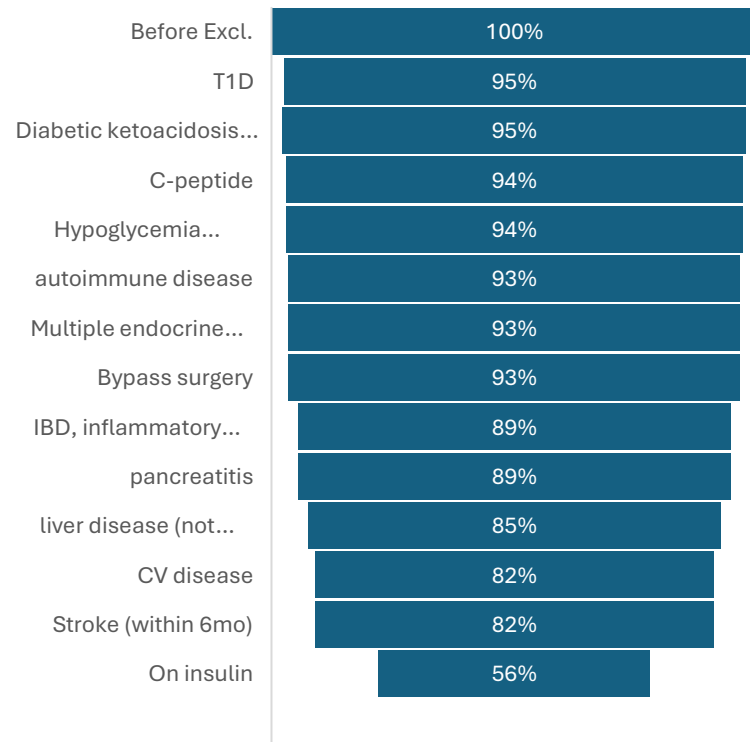
✓ Project interest

✓ Budget

Optimize Protocol Design -- data-driven approaches

- A pivotal study protocol of a competitor device
  - T2D patients treated with basal insulin
- Individual Inc./Excl. criterium all looked reasonable
- Combination of them screened out almost all patients

.......not an executable protocol

Optimize Protocol Design -- data-driven approaches

Before Excl.	100%
T1D	95%
Diabetic ketoacidosis...	95%
C-peptide	94%
Hypoglycemia...	94%
autoimmune disease	93%
Multiple endocrine...	93%
Bypass surgery	93%
IBD, inflammatory...	89%
pancreatitis	89%
liver disease (not...	85%
CV disease	82%
Stroke (within 6mo)	82%
On insulin	56%

1. If age upper limit increases from 65 to 70, output increases by 31%

2. If BMI range narrows from 25-40 to 27-40, ...

3. If HbA1c range changes x to y,.........

4. If eGFR changes from x to y, ...

Key Considerations ---Post-market Phase

- Business plan, long-term needs
- Multiple projects, multiple priorities
- Build in-house capabilities
  - Project management
  - Study start up
  - Monitoring
  - Safety
- Take advantage of CRO functional services
  - Data management
  - Statistics
  - Health economics
  - monitoring

Medical Device Clinical Development Program

Preserve flexibility

Optimize endpoints

Optimize success

Optimize efficiency

Pilot

Post-market

- Proof of concept
- Procedural development
- Device iterations

FIH/Feasibility

- Test target patient population
- Generate data for pivotal study design
- Test pivotal device

- Generate data to support regulatory approval
- Generate data to support reimbursement
- Make or break the company

Pivotal

- Meet regulatory requirements
- Generate evidence to support reimbursement and market adoption