PSIDE Creation & Maintenance

Agenda

- Introduction to PSIDEs
- Sponsor and Investigator Roles
- IDE Submission Form
- IDE Maintenance
- Common Problems
- Additional Resources

PSIDE

Physician Sponsored Investigational Device Exemption

Sponsor & Investigator Roles

Sponsor Responsibilities

- Choosing qualified investigators
- Gaining FDA and IRB approval
- Selecting monitors
- Device control
- Informing investigators
- Monitoring
- Maintaining records
- Sponsor reports
- Labeling
- Monitoring device promotion

Investigator Responsibilities

- Managing informed consent
- Supervising device use
- Financial disclosure
- Disposing devices
- Maintaining records
- Investigator reports

PSIDE Submission Form

IDE Devices

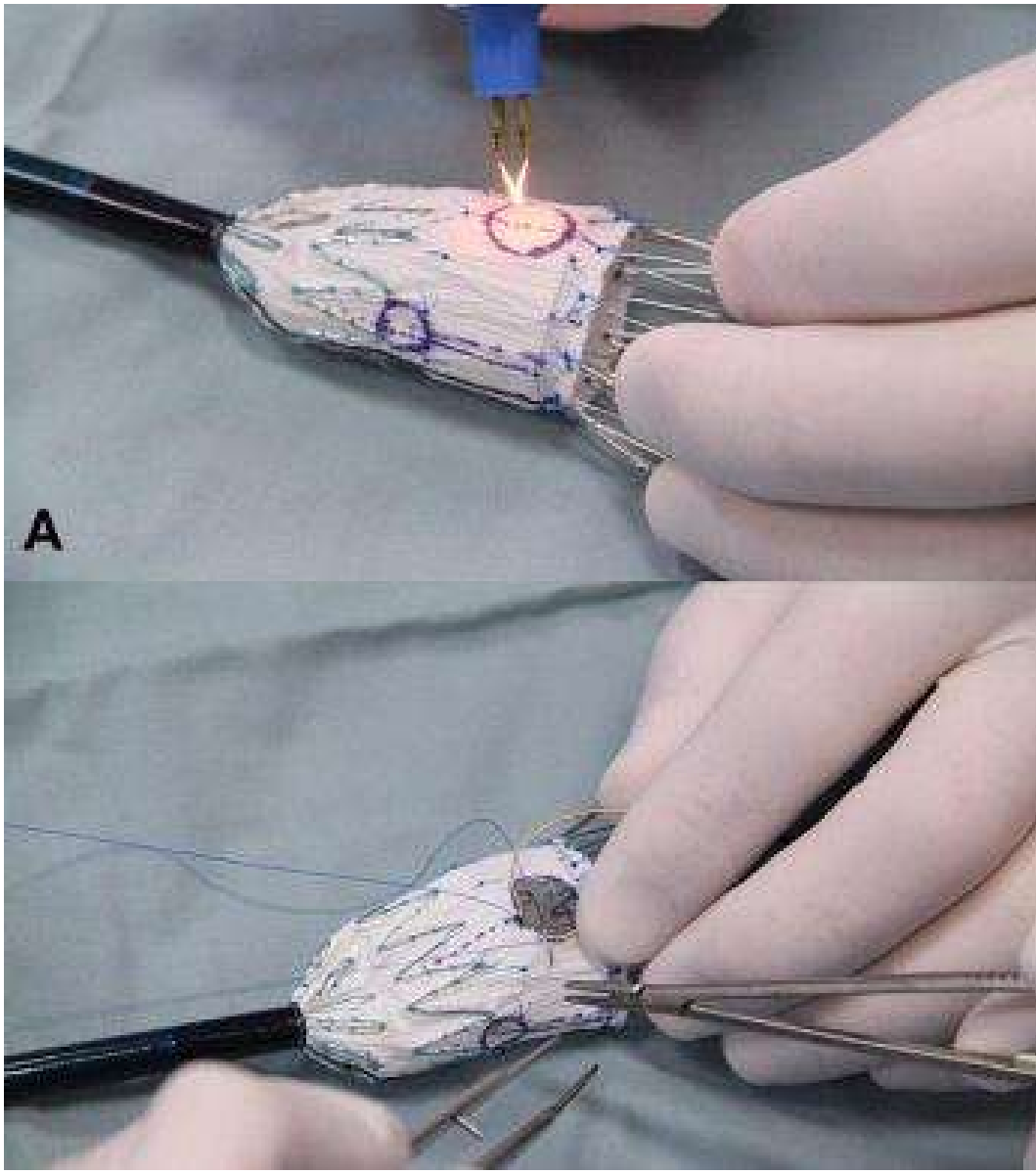
- Significant Risk Devices
- Nonsignificant Risk Devices

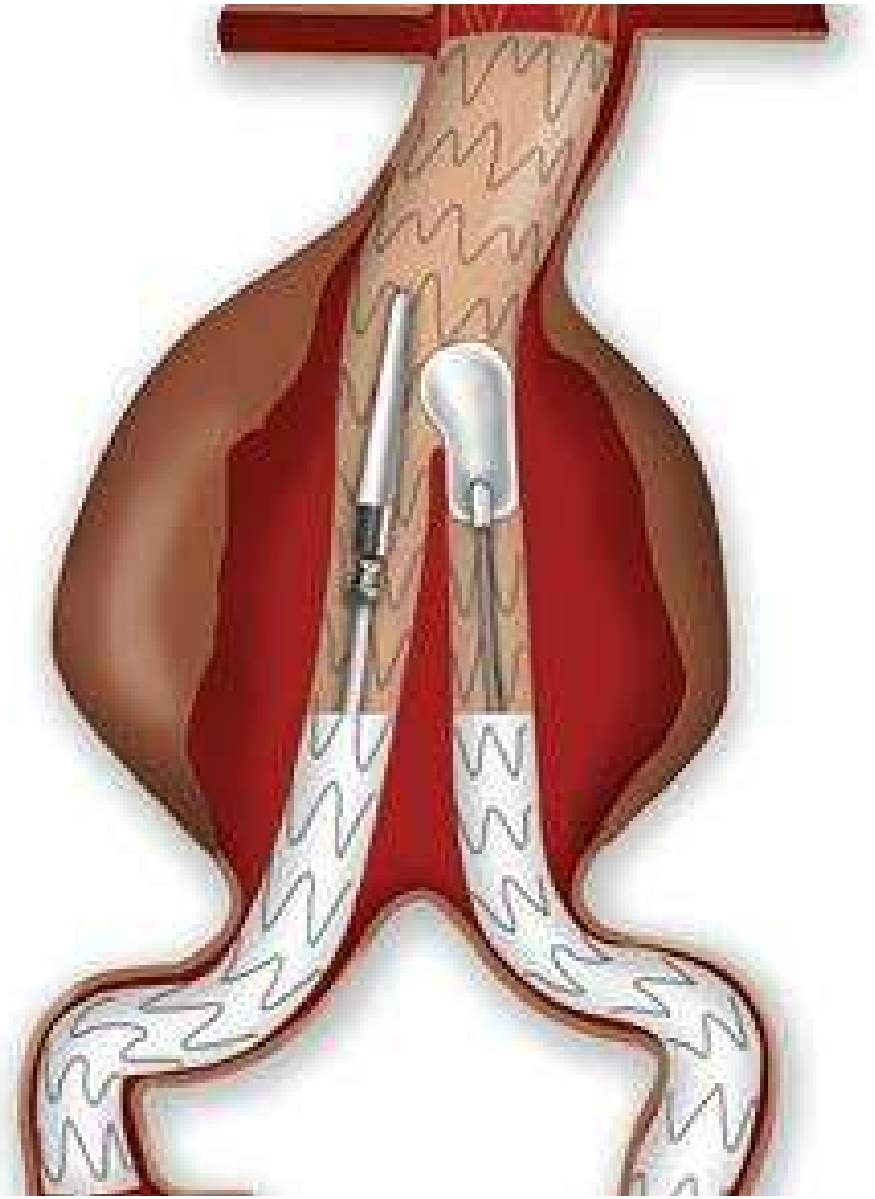
Purpose

- Modifying a device
- Using for an unintended use

Modifying a Device

- Reasonable assurances for no harm
- Durability testing data
- Prior data on the device





Unintended Use

- Reasonable assurances for no harm
- Prior data on the device

Creating the IDE Submission

- Reach out to the FDA early
- Cover Letter
- IDE Application
- IRB Approval
- FDA Approval
- FDA Checklist

IDE Cover Letter

- Statement of original IDE
- Device Information
- Sponsor Contact Information
- Manufacturer Information
- Correspondent Information
- Any Q-Submissions/Pre-Submissions or Study Risk Determination (SRD) Q-Submission
- Waiver Requests
- Referenced Files

IDE Application

- Name and Address of Sponsor
- Report of Prior Investigations
  - Bibliography of Publications
    - Evaluate Safety and Effectiveness
  - Adverse Information
    - Published and Unpublished
  - Any requested significant publications
  - Summary of unpublished information
- Investigational plan
  - Protocol
  - Risk Analysis
  - Device Description
  - Monitoring Procedures
  - Additional Records and Reports

IDE Application Continued

- Descriptions of the following for all steps in devices life
  - Methods
  - Facilities
  - Controls
- Signed Investigator Agreement and Certification
- IRB Information
- Institution Information
- Amount Charged per Device
- Copies of all labeling for the device
- Copies of all informed consent forms
- Any additional information

Uploading the IDE Application

- Want a valid eCopy
- Ecopy Guidance Document
- IDE approved by FDA in 30 days

Maintaining your PSIDE

Sponsor Reports

- Unanticipated Adverse Device Affects
- Withdrawal of IRB or FDA Approval
- Current List of Investigators
- Annual Progress Reports
- Recalls and Device Disposition
- Final Report
- Failure to Attain Informed Consent

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Unanticipated Adverse Device Affects

- 10 days to report

Withdrawal of FDA or IRB Approval

Withdrawal of IRB Approval:

- Notify FDA
- Notify any IRB
- 5 Working Days

Withdrawal of FDA Approval:

- Notify IRB
- Notify any other investigators
- 5 Working Days

Current List of Investigators

- Current list to FDA
- Every 6 months
- Ask about FDA waiver

Annual Progress Report

- Submit to IRB and FDA
- Guidelines on FDA website
  - Under IDE Reporting

- Include:
  - Basic Elements
  - Study Progress
  - Risk Analysis
  - Other Changes
  - Future Plans

Recalls and Device Disposition

- 30 days to notify
- Notify FDA and reviewing IRBs
- Any return, repair, or disposal of a device

Final Report

- Notify FDA and IRB
  - Within 30 working days
- Submit final report to FDA and IRB
  - Within 6 months

- Final report includes:
  - Basic Elements
  - Study Progress
  - Risk Analysis
  - Other Changes
  - Marketing Application or Future Plans

Failure to Attain Informed Consent

Notify FDA

- Within 5 working days

Investigator Reports

- Unanticipated Diverse Device Affects
- Withdrawal of IRB Approval
- Progress Reports
- Deviations from the Investigational Plan
- Annual Progress Reports and Final Reports

Deviations from the Investigational Plan

- Notify IRB
  - Within 5 working days
- Informed Consent
  - Notify IRB within 5 working days
- Final Report
  - Submit to IRB within 3 months of termination
- Other Reports
  - Provide information when requested

Overall Reporting Takeaways

- Lots of reporting
- Dedication for upkeep

Sponsor Records

- All correspondence
- Shipment records
- Device disposal records
- Signed investigator agreements
- Complaints and adverse device effects
- Any FDA specified records

Investigator Records

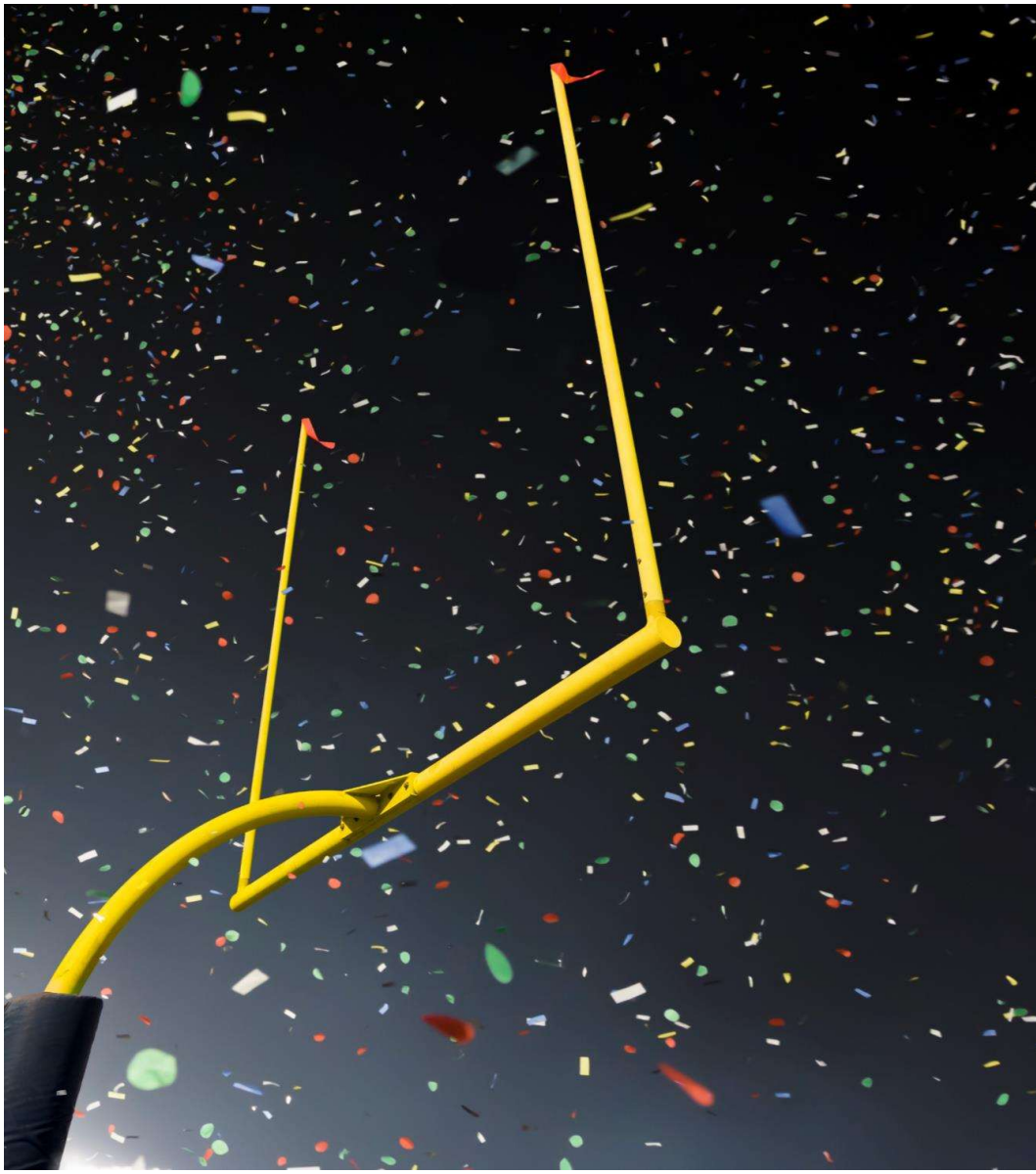
- All correspondence
- Device records
- Subject records
- Protocol and documentation
- Any FDA specified records

Common Deficiencies & Struggles

- Describing an End Goal
- Inadequate Investigational Plan
- Incorporating and Reporting Technical Information and Prior Investigations
- Inadequate/Incomplete Design and Manufacture
- Understanding the cost of an IDE

End Goal

- Device approval
- Gateway to a clinical trial



Investigational Plan

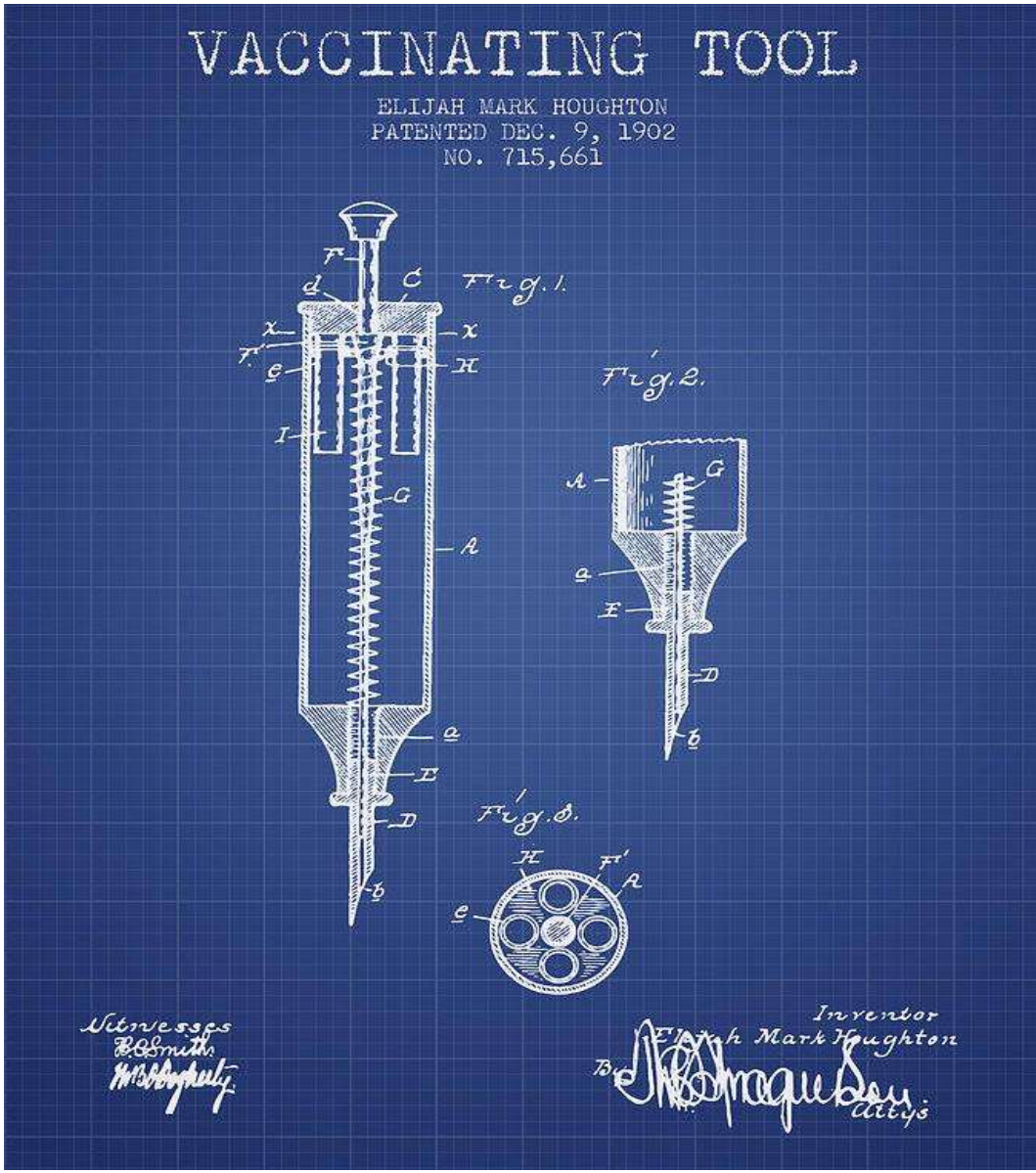
Be detailed!

Required Technical Information

- Request Device Master File
    - Contact company
        - Local medical sales associate
        - Product specialist
- Durability information
    - Search companies online
    - Request to rent company testing devices

Inadequate/ Incomplete Design and Manufacture

- Reach out to:
  - Medical Sales Associate
  - Product Specialist
- Ask questions!



Cost of (PS)IDEs

- Expensive
- Cost of manufacturing and testing device
- Data collection and analysis
- Staff

Grants & Aid

- Funding opportunities
  - Fellowship, Educational, & Research Grants
- Check out templates & grant portal
  - www.goremedical.com/grants
- Information already collected for PSIDE application
- If any issues, please email
  - grants_program@wlgore.com

Final tips & takeaways

- Reach out to the FDA early
- Apply for grants & know your budget
- Make sure all the technical information is in order
  - Device testing
  - Reach out for the device master file
- Seek feedback
- Be detailed in your applications and reports

Thank you

Sources & Photos

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- Davidson, Andie. "Testing New Generation Medical Devices." *Quality Magazine.* June 2nd, 2015. Date accessed: April 19th, 2024. https://www.qualitymag.com/articles/92646-testing-new-generation-medical-devices