

Operational Challenges and Opportunities for Novel Research Infrastructure

*Novel Approaches to IDE Studies Using the
NCDR: ACC View*

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Device Advice: Comprehensive Regulatory Assistance

How to Market Your Device

▶ Investigational Device Exemption (IDE)

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Device Advice: Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)'s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study is initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an IDE approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
- informed consent from all patients;
- labeling for investigational use only
- monitoring of the study and;
- required records and reports.

An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act (Act) that would apply to devices in commercial distribution. Sponsors need not submit a PMA or Premarket Notification 510(k), register their establishment, or list the device while the device is under investigation. Sponsors of IDE's are also exempt from the Quality System (QS) Regulation except for the requirements for design control.

Good Clinical Practices (GCP)

Good Clinical Practices (GCP) refers to the regulations and requirements that must be complied with while conducting a clinical study. These regulations that apply to the manufacturers, sponsors, clinical investigators, institutional review boards,

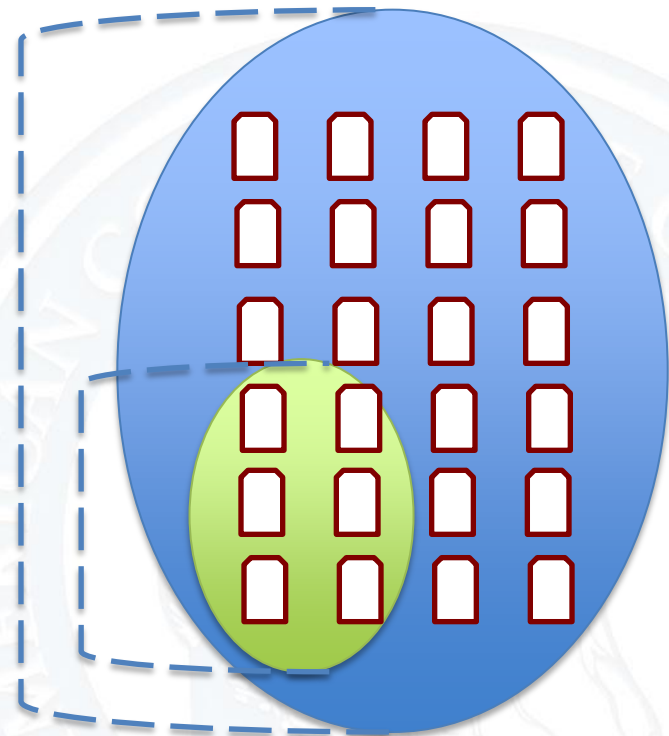


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Registries/IDEs

- Access to larger volume of pts
- Eliminate redundant data collection
- Existing data collection
- Granular clinical data
- Data quality procedures
- Clinical support for data interpretation and data capture
- Collect a large amount of data quickly
- Extended surveillance

Registry Participants



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IDE Sponsor



Regulations
Risks
Funding



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Traditional Approach

Novel Approach

\$\$\$

Longer



\$

Shorter

A Spectrum of Approaches

Recruitment	select among existing participants	
Site Training Support	build upon existing training structures	
IRB/Informed Consent	traditional	modified
Site Monitoring	onsite and remote monitoring	registry completeness & select audits
Data Capture	registry + more	registry only
Adjudication	clinical event committee	algorithmic



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Time for a Paradigm



**KEEP
CALM
THERE'S A
PARADIGM
SHIFT
GOING ON**



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