

Medical Device Regulation

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Medical Product Project Assessment

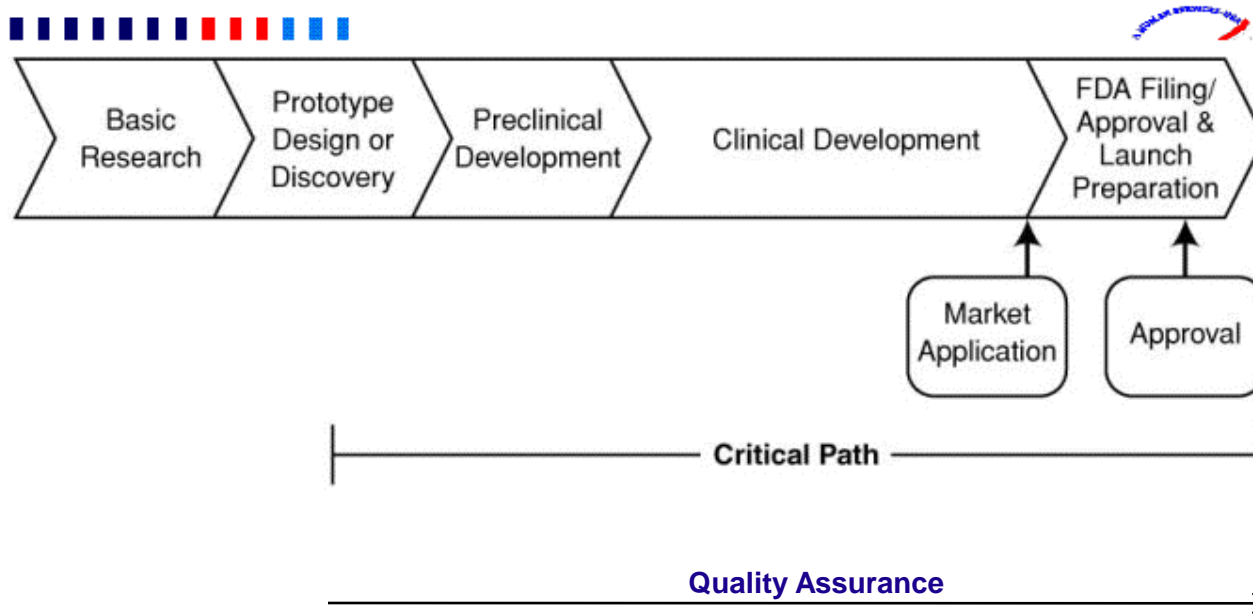
- Medical need
- Technological solution
- Market Analysis
- Patentability
- Feasible markets and competitors
- Survey on scientific evidence
- **Regulatory and Reimbursement**
- Funding



Premarket Life Cycle

US market as an example

The Critical Path for Medical Product Development



Medical Device Definition

- *Used for the diagnosis, treatment or prevention of disease or condition*
- Affects the structure or function of the body
- Does not achieve its function through chemical action
- Is not metabolized to achieve effect

Medical Device Examples



Food & Drug Administration



*Protecting Consumers,
Promoting Public Health*

U.S. Food and Drug Administration

Food & Drug Administration

FDA is part of the Public Health Service (PHS) within the Department of Health and Human Services (HHS).

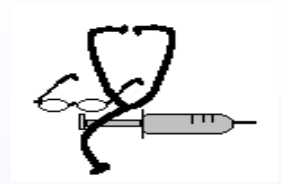
FDA is headed by a commissioner appointed by the President with Senate consent.

Food & Drug Administration

- Center for Biologics Evaluation and Research (CBER)
- *Center for Devices and Radiological Health (CDRH)*
- Center for Drug Evaluation and Research (CDER)
- Center for Veterinary Medicine (CVM)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Tobacco Products (CTP)
- Office of Regulatory Affairs (ORA)

Types of FDA Regulated Products

- *Medical Devices (including IVD) and Radiation Emitting Products- Center for Devices & Radiological Health*
- **Drugs- Center for Drugs Evaluation & Research**
- **Biologics- Center for Biologics Evaluation & Research**
- **Combination Products- Office of Combination Products**
- **Food and Cosmetics- Center for Food Safety & Applied Nutrition**
- **Animal feed and Drugs- Center for Veterinary Medicine**



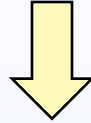
Pre-Submission Consultation

Sources of Information

- **The FDA provides advice and feedback to sponsors:**
 - Device Advice Website
 - Division of Small Manufacturers, International and Consumer Assistance (**DSMICA**)
 - Guidance documents
- **Pre IDE meeting** – An early collaboration meeting

Critical Path

Claim/Intended Use



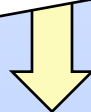
Device CI

Risk / Benefit

where

Benefit Outweighs Risk

and clinical)



filing

Market /clearance approval

Claim

Intended Use/Indications

1. Identification of function
2. Identification of tissue type an organ system or Identification of a specific organ
3. Identification of a particular disease or target population
4. Identification of an effect on clinical outcome

Tool Claim

Clinical Claim

Tool Vs. Clinical Claim

Cardiac Pacing device

Tool:

The Frontier Biventricular Cardiac Pacing System is indicated for **maintaining synchrony of the left and right ventricles** in patients who.....

Clinical:

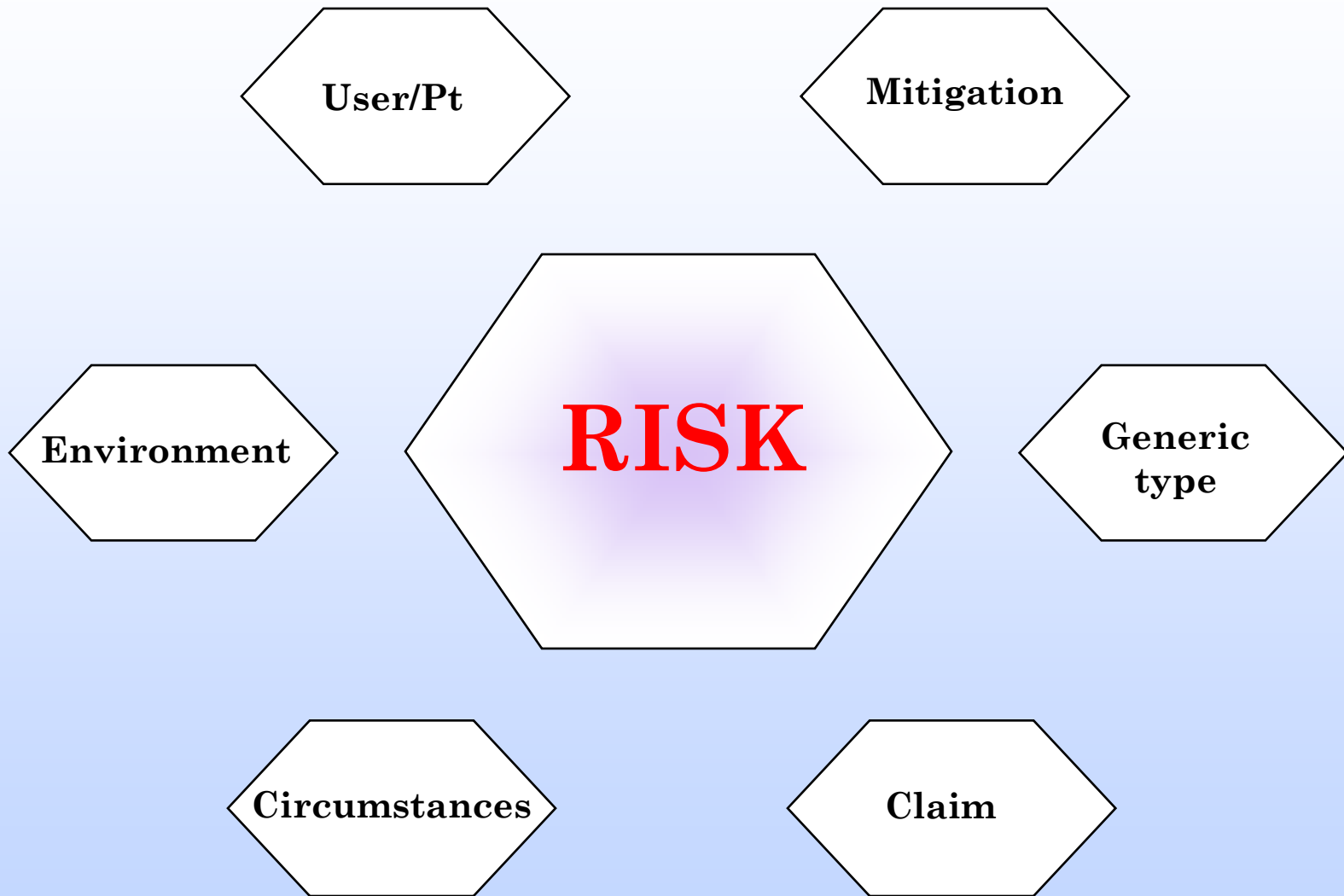
The InSync model 8040 pulse generator is indicated for **the reduction of the symptoms of moderate to severe heart failure** (NYHA Functional III or IV) in those patients who.....

Classification

Classifications/Reclassifications are based upon:

- **Claim**
- **Risks**
- **Generic type** of device and similarity to devices of the same type (Substantial Equivalency, SE)

Definition of Risk



Classification

*Medical devices are divided into three regulatory classes based on the **risk and level of control necessary to assure their safety and effectiveness.***

- **Exempt** – Class I & II (SE)
- **510(k)** – Class I, II (SE)
- **PMA** – Class III

Low

Risk Level



High

- **De Novo 510(k)** --> 510(k) New technologies & not class III risk level
- **HDE** – Rare diseases

Classification Codes

*1700 generic groups of devices
classified within 16 medical specialties*

An example of classification record:

Device: COMPUTER, DIAGNOSTIC, PROGRAMMABLE

Product Code: 74 DQK

Regulation No.: 870.1425

Class: II

Medical Specialty: Cardiovascular

Classification

*Medical devices are divided into three regulatory classes based on the **risk and level of control** necessary to assure their safety and effectiveness.*

• **Exempt** – Class I & II (SE)

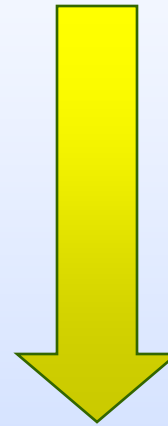
Low

Risk Level

• **510(k)** – Class I, II (SE)

• **PMA** – Class III

High

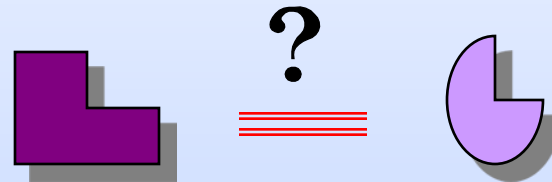


Regulatory Pathway

510(k) vs. PMA



510(k) devices must only demonstrate that there are *as safe and as effective as* similar device/s (predicates) already marketed → **SE determination**



PMA devices must demonstrate, *on their own merit, safety and effectiveness* through valid scientific evidence

SE Determination (510(k))

A device is considered **SE** if, in comparison to a predicate it:

has the same intended use **and** the same technological characteristics

OR

has different technological characteristics but does not raise **new questions of safety and effectiveness**; **and** it is demonstrated that the device is at least as safe and effective as the legally marketed device.

CDRH Performance Data

Actions through 31 March 2010

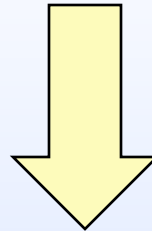
	FY 2008	FY 2009	FY 2010 (Apr)
510(k)	3,848	4,103	1,884
PMA	33	41	11

Device Approval in Europe

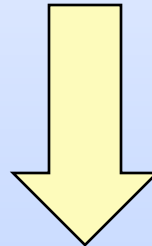


Device Approval in Europe

European Commission (Brussels)



Competent Authority of each
Member State



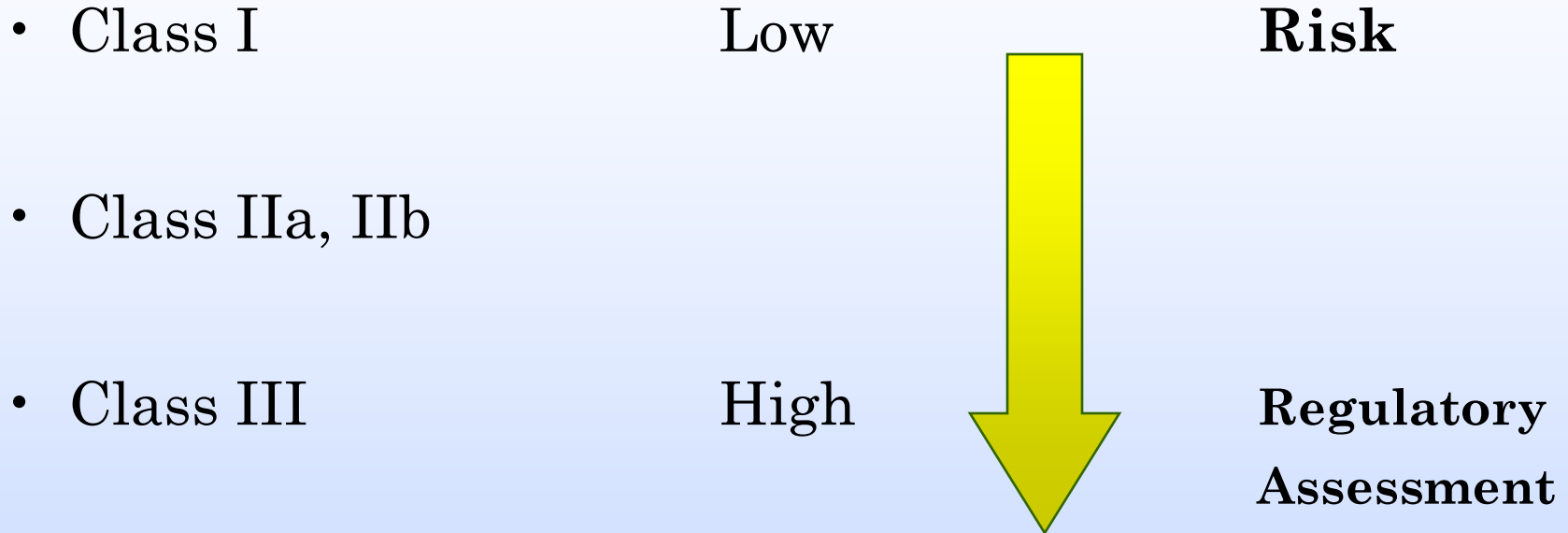
Notified Body

Device Approval in Europe

- **EU Member States:** 47 European countries
- The CE marking system relies on "**Notified Bodies**" (**NB**) to implement regulatory control over medical devices
- Notified Bodies are independent commercial organizations that refer the relevant Member State
- **A company is free to choose any Notified Body**
- **Governing rules:** Directives (issued by the EU commission) and Guidelines + Local legislations

Regulatory Pathway

Classification:



**ALL DEVICES MUST PRESENT CLINICAL EVIDENCE
FOR MARKET APPROVAL**

Device Approval in Europe

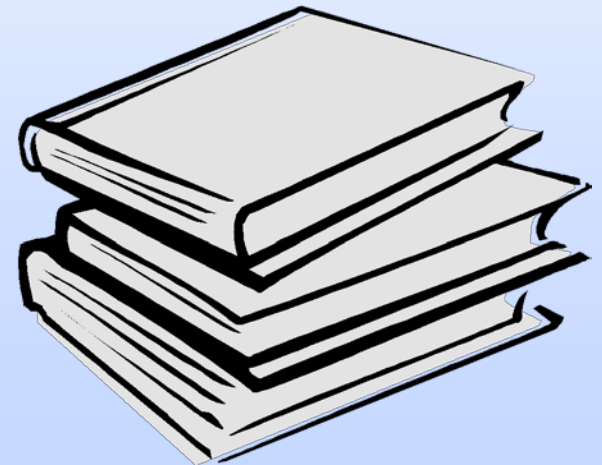
Market

Risk / Benefit

where

Benefit Outweighs Risk

Clinical (Human) Data



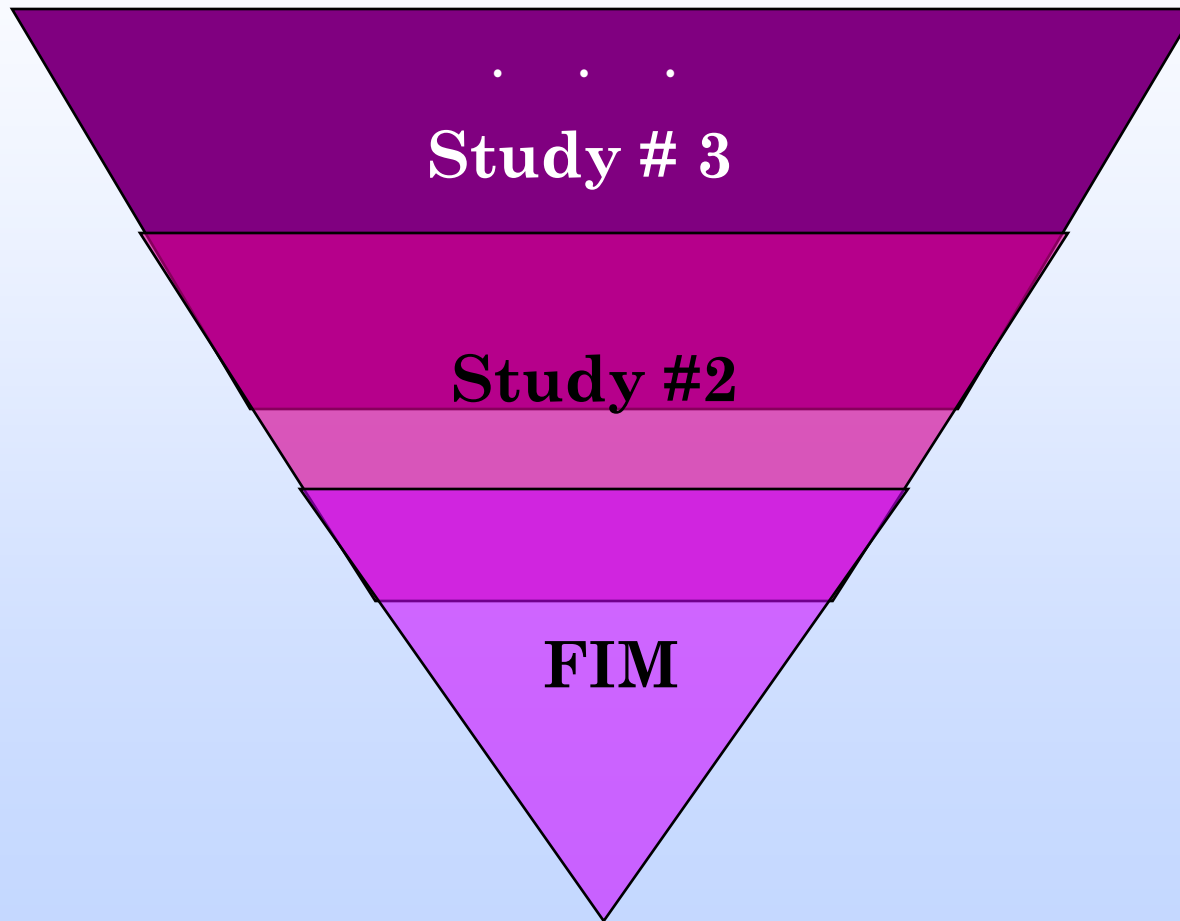
Clinical Evidence

Clinical data is the result of:

- Clinical studies
- Postmarket field use

- Published data – Databases (mainly safety); Scientific articles

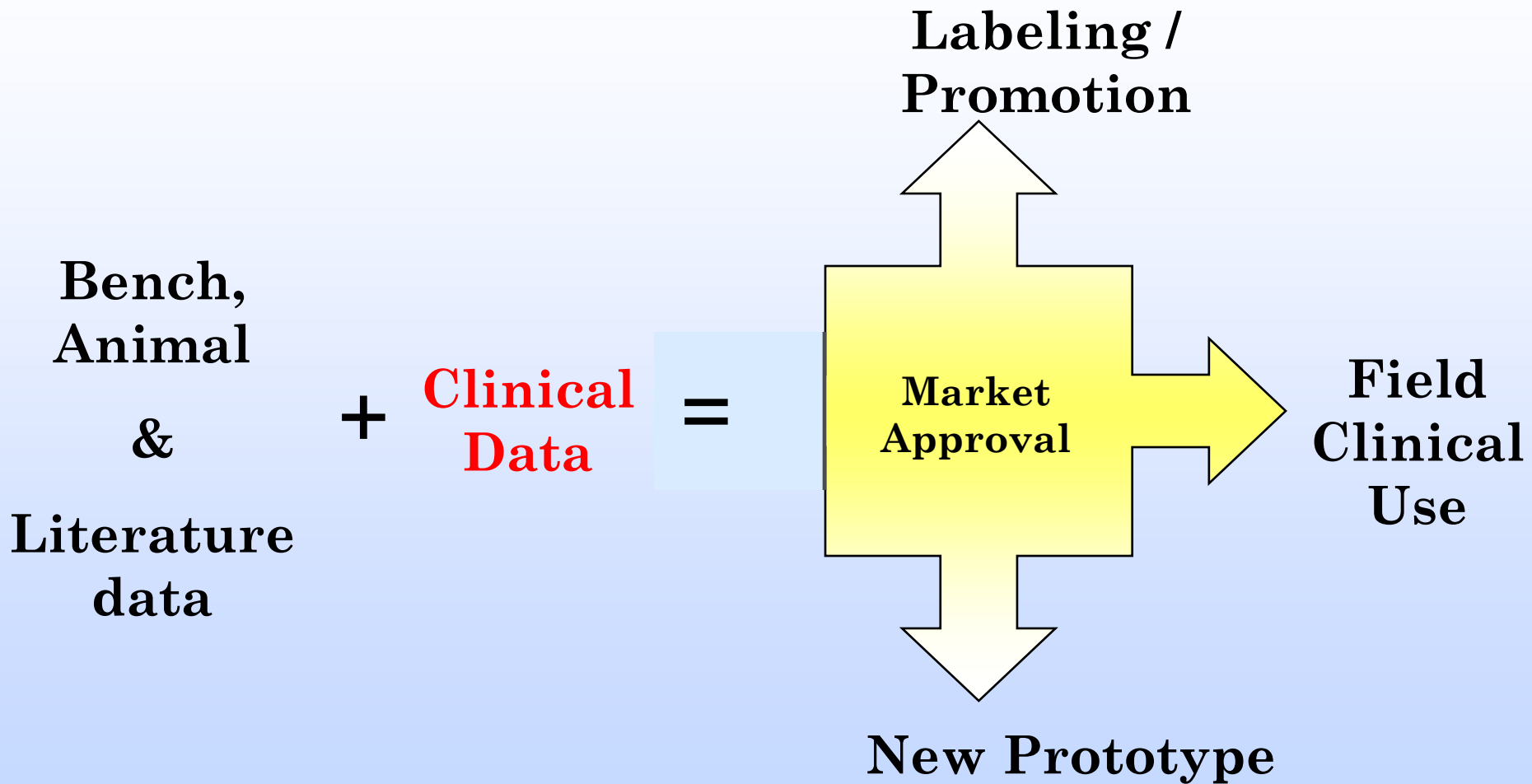
Clinical Evidence



Clinical Nutshell

- Global Clinical plan (pre and post market)
- Design of study
- Selection of sites and investigators
- Generation of study documentation
- Approval of regulatory authorities
- Commercial agreement
- Conduct of study (Good Clinical Practice)
- Data analysis and reporting/publication

Product Life Cycle



Regulation *is about*
Product development
Liability
Due Diligence
and
Market proposition

Thank You

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