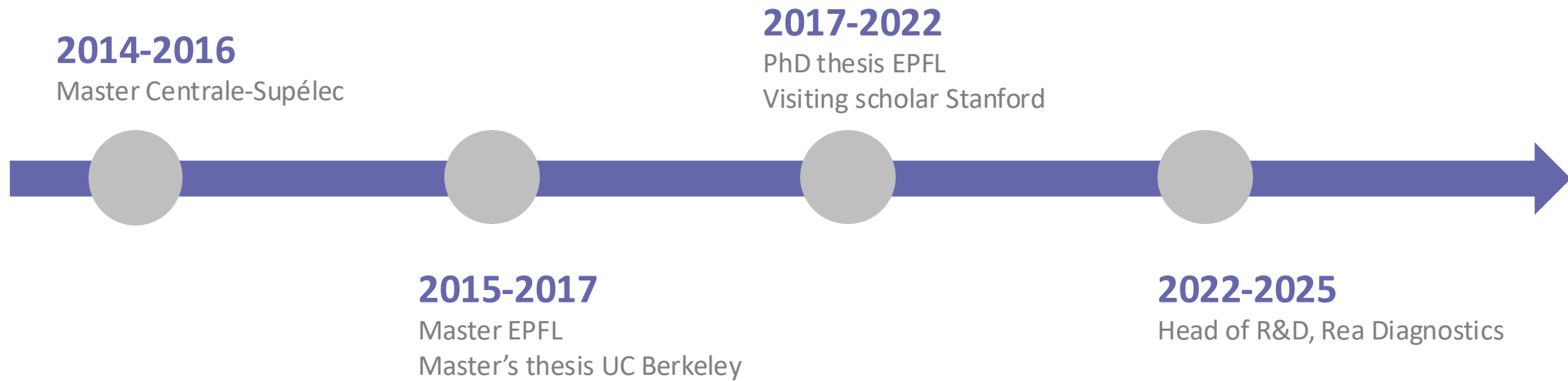


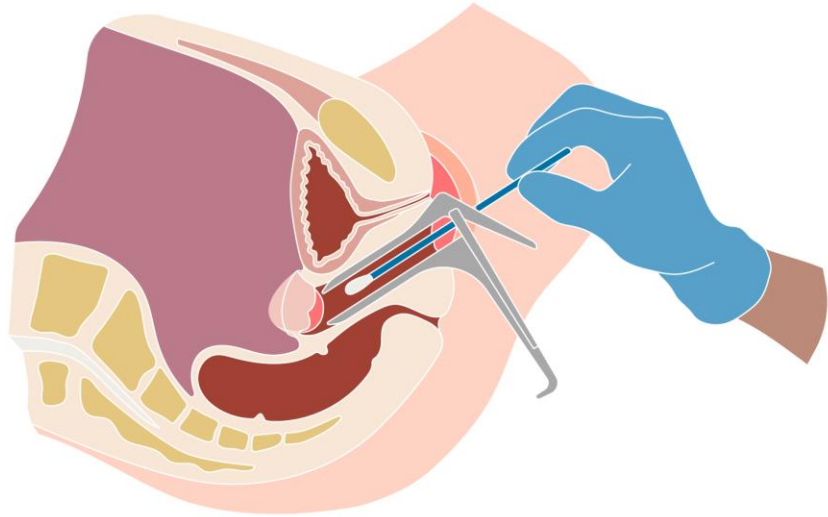
The role of regulations in the medical device industry

Pierre-Emmanuel Thiriet, PhD

| About myself



| Rea Diagnostics' vision



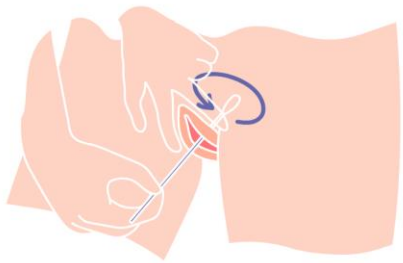
Invasive procedure

- Low accessibility (only done in clinics)
- High cost
- Reduce quality time with doctors

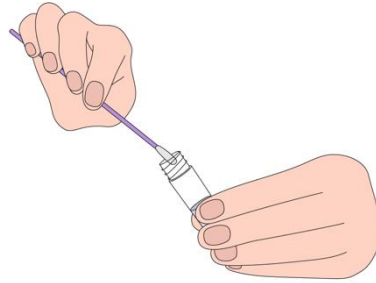
Price > 200 CHF

15 minutes

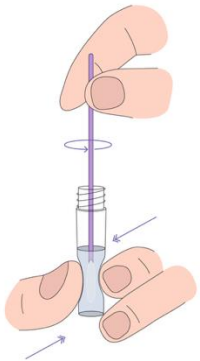
Rea Diagnostics' vision



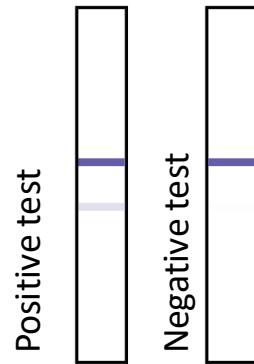
1. Sample collection



2. Sample insertion



3. Sample resuspension



4. Test readout

Non-invasive procedure

- Available in pharmacies
- Low cost
- Pre-screening of patient prior to healthcare visit
- Increase well-being at the end of pregnancy
- Negative predictive value: >98%

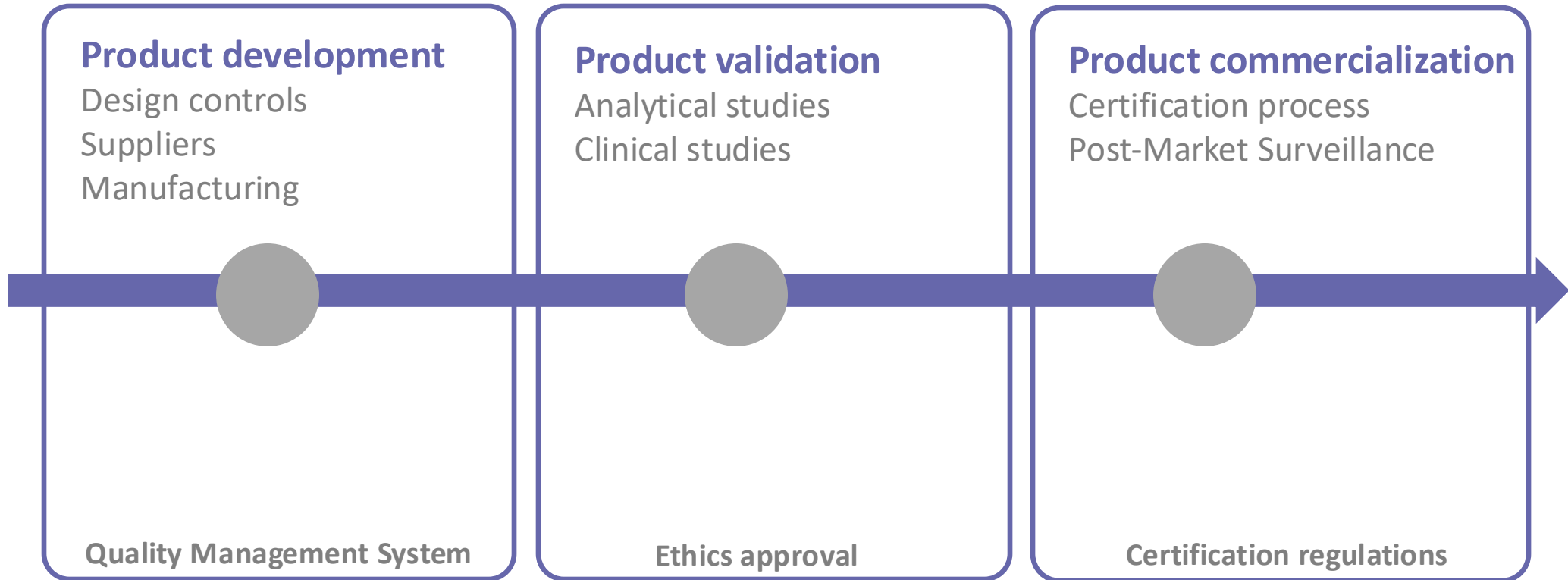
| Definition of regulation

*A regulation is a rule made and maintained by an **authority**, typically a governmental agency, to control or govern **conduct** within its jurisdiction.*

*Governmental administrative **agencies** have specific authority to regulate conduct within their areas of responsibility. These agencies are delegated legislative power to create and enforce rules, known as “regulations.”*



| Product life pipeline



Product development & Quality Management System

Why is there a need for Quality management systems?

PIP scandal



Source: CNN

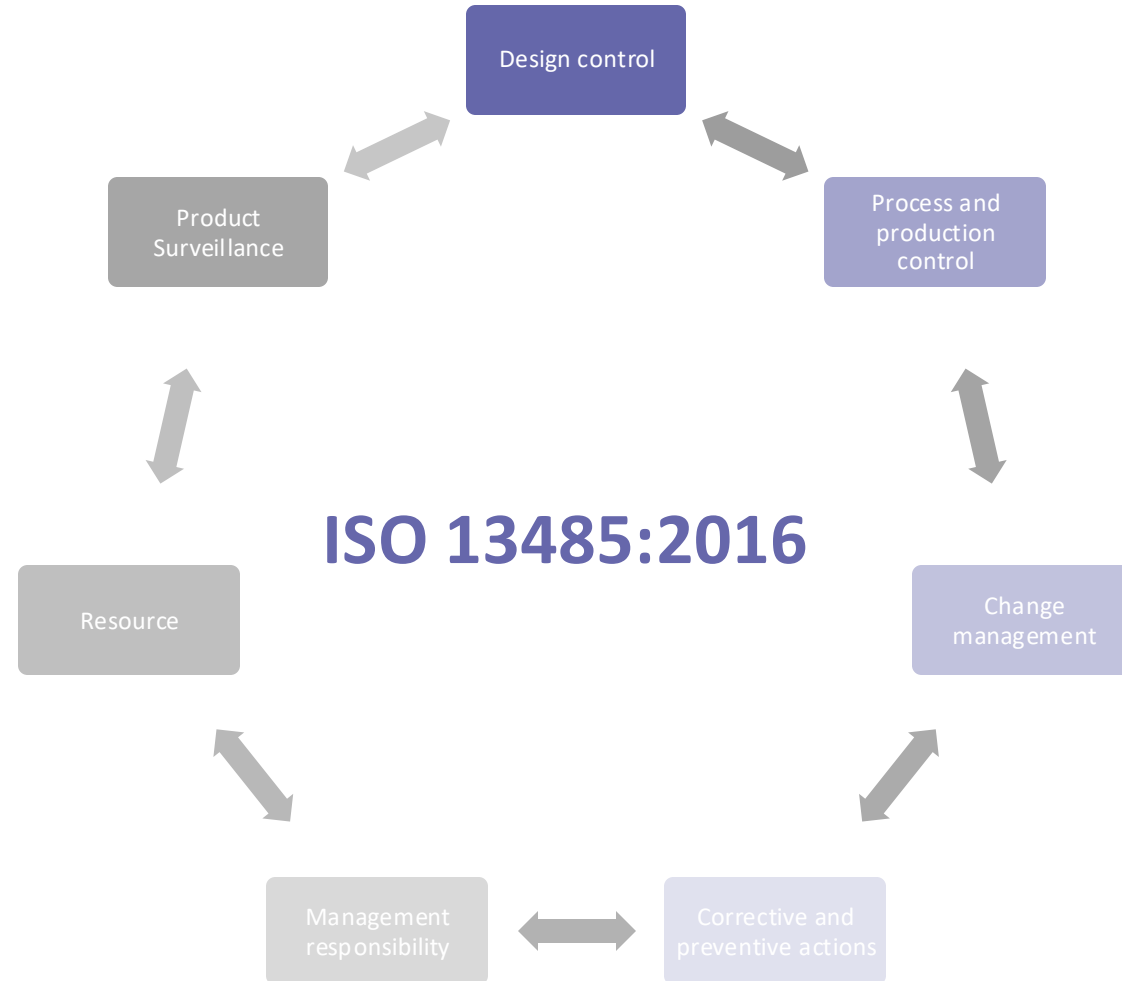
- Breast cancer implants manufactured with industrial grade silicone instead of medical grade
- 500% more chances of rupture or leak
- 15 tumors, 1 death
- They were notified before audits and would hide problematic reagents.



Change in regulation, surprise audits

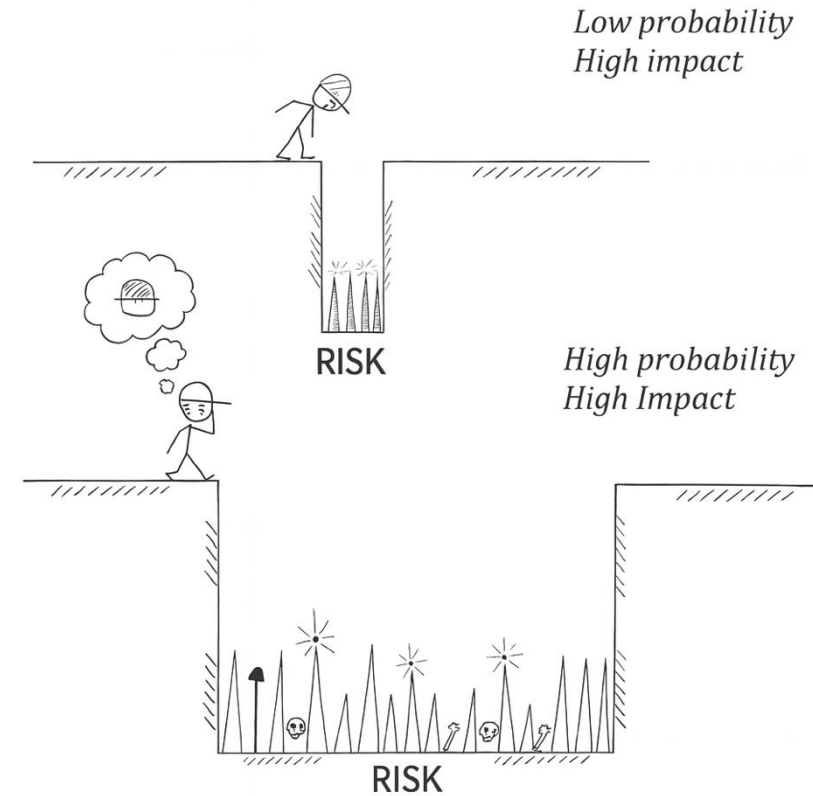
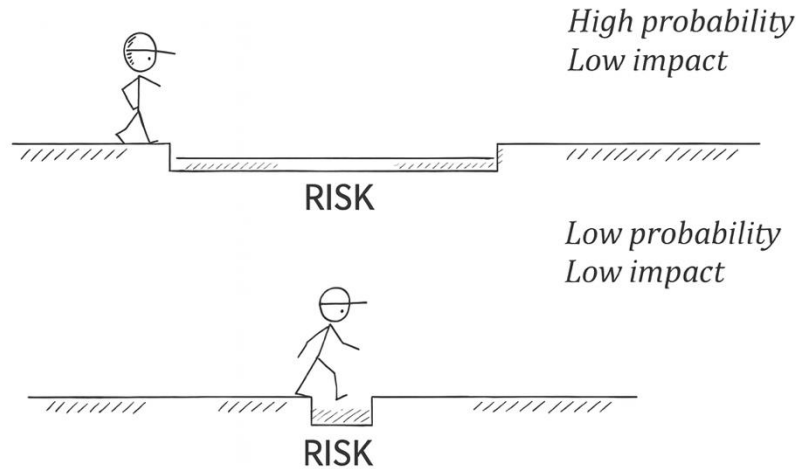
Product development & Quality Management System

Structure of the ISO 13485 norm



Product development & Quality Management System

Risk-driven approach



1. Inherent safe design
2. Protective measures
3. Information to user

| Clinical studies: Validating the performance of the device

A bit of history...

- **5 centuries BC:** Hippocratic Oath



Unethical behavior with war prisoners and deported people

- **August 1947:** Nuremberg code (Best interest of participants)



Thalidomide disaster (severe fetal malformation)

- **June 1964:** Declaration of Helsinki

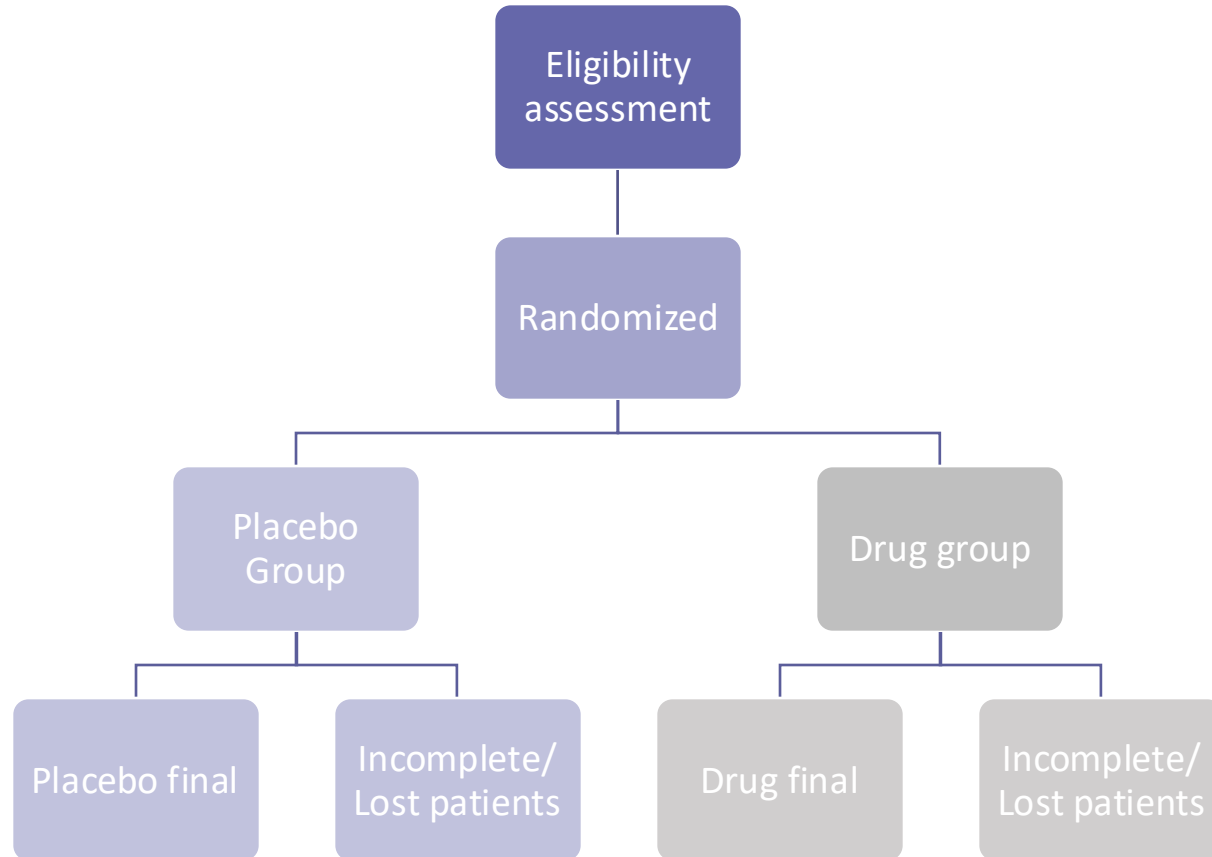


Tuskegee Syphilis study

- **July 1996:** International Conference on Harmonization of Good Clinical practice (ICH-GCP)

Clinical studies: Validating the performance of the device

Gold standard: Randomized double-blinded placebo controlled clinical study

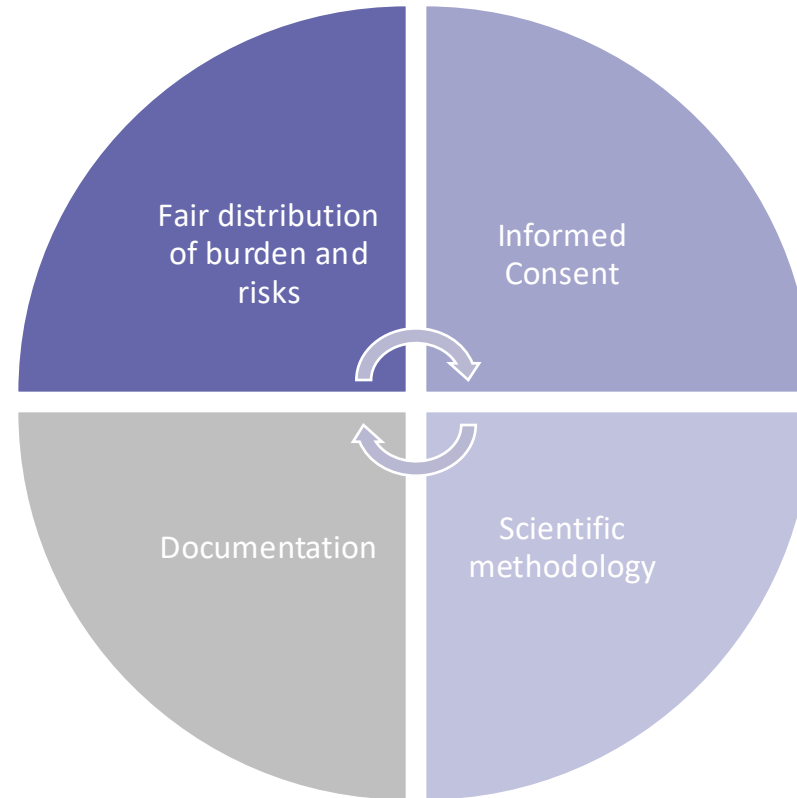


A bit of vocabulary:

- Prospective vs Retrospective
- Observational vs Interventional
- Randomization
- Double-blinded
- Placebo Controlled

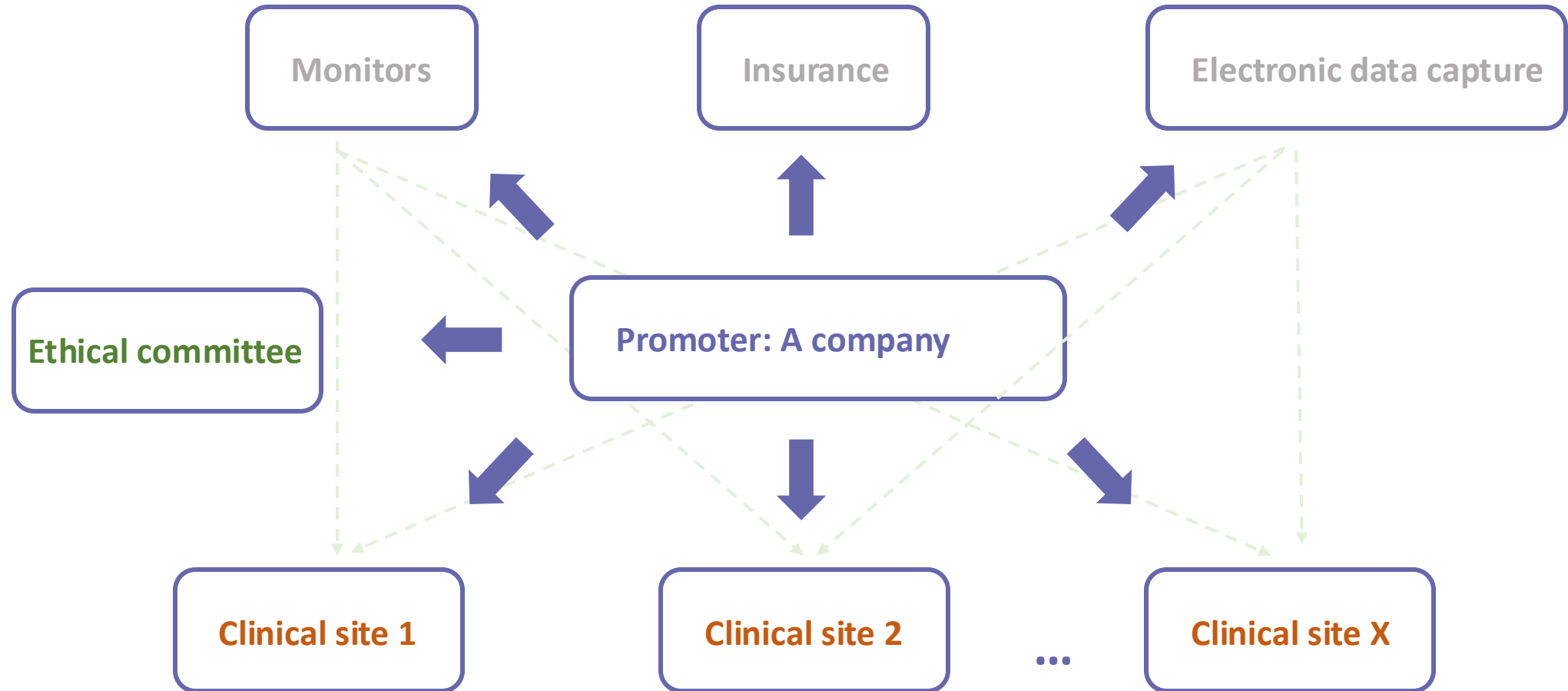
| Clinical studies: Validating the performance of the device

Notions of ethics



Clinical studies: Validating the performance of the device

Mapping the main stakeholders



Product certification

Theranos scandal: Need for thorough certification process

The promise

- 1 drop of blood in nanocontainers, tens of biomarkers
- Cheap, fast and effective

The fraud

- No technology developed (Fake it until you make it)
- 900'000 test/year carried on miscalibrated machines

The consequences

- Undetected cancer and heart attacks
- Loss of 724 millions of investment
- Jail sentence of 11 years

The reasons

- Little control on laboratory-developed test
- A lot of lies and intimidation



Source: Forbes

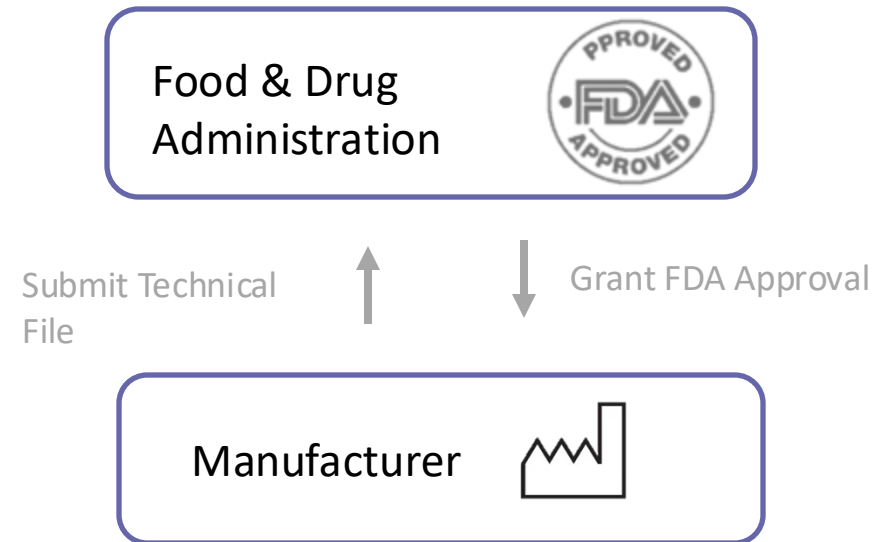
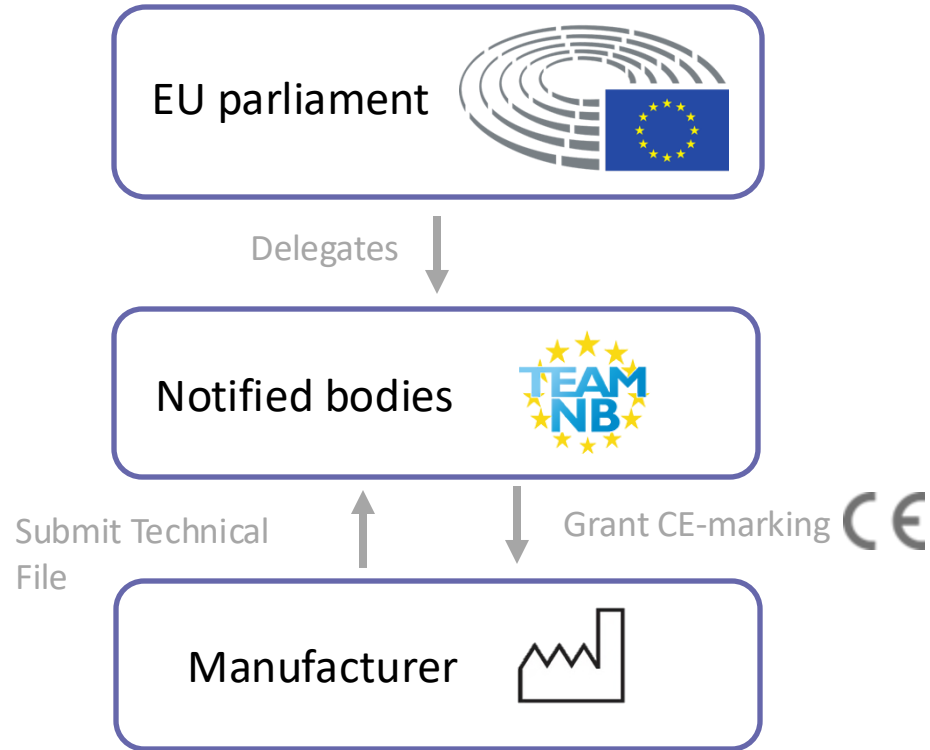
| Product certification

Technical documentation content



Product certification

The regulatory landscape



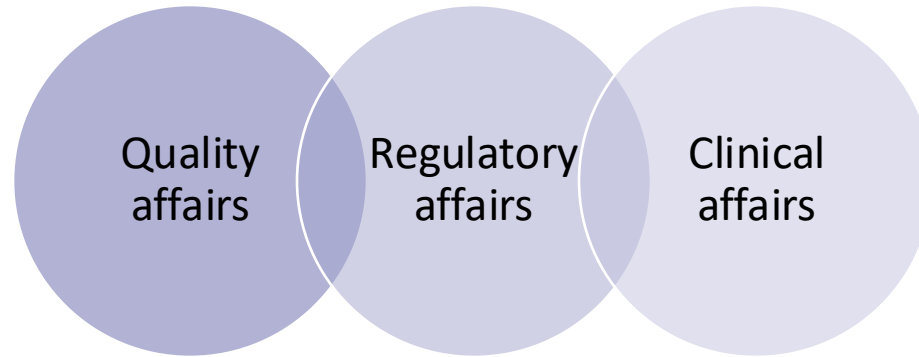
Documents to help you: ISO standard, FDA/ EU regulations...



This costs a lot...

| Take-home message

- Activities come hand in hand
- Inherently multidisciplinary
- Need in the Swiss ecosystem for these profiles



Thanks for your attention