

Clinical Evaluation Plan Planning for clinical data



Why clinical studies on MD?



- ➤ To get MD to the market
- ➤ To keep MD in the market
- > To go from idea to marketable device
- > To extend indications

>...



► It takes a PLAN!

Clinical evaluation



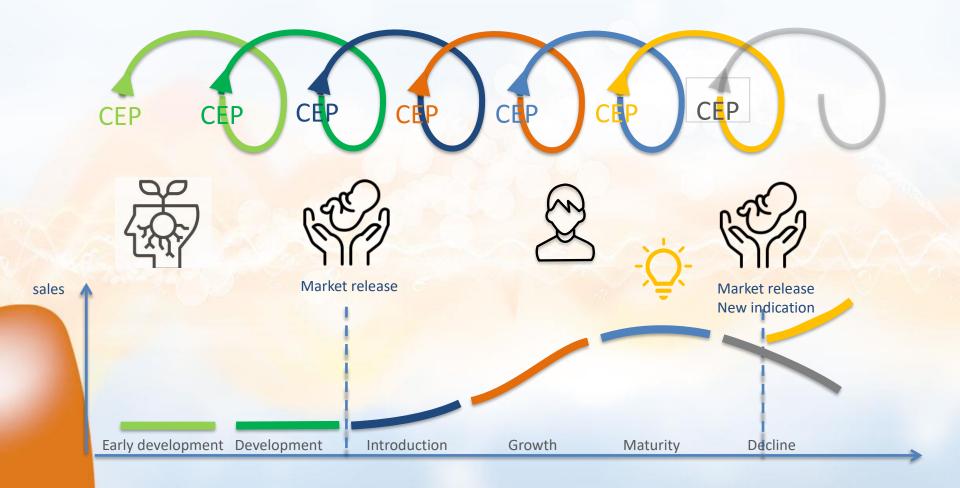
A systematic and planned process to continuously

generate, collect, analyse and assess
the clinical data pertaining to a device
in order to verify the
safety and performance, including clinical
benefits, of the device
when used as intended by the manufacturer

24-9-2024 ACS Proprietary

Over lifetime of the device





Getting a device to market





Clinical study

- Safety
- Benefit

Data on equivalent devices

- Performance / Benefit / Safety
- Literature or with contract

Own data

- bench test
- animal

SotA on medical condition / indication

- Alternative treatment
- Similar devices
- Safety / benefit
- Benchmarks benefit/risk

Keeping a device in market



➤ Update CEP for clinical data

Data on equivalent devices (MDD -> MDR)

🦯 Performance / Benefit / Safety

PMCF data

- Literature on device
- Customer questionnaires
- (Subject data)

PMCF

study

- Safety
- Benefit

PMS data

Safety

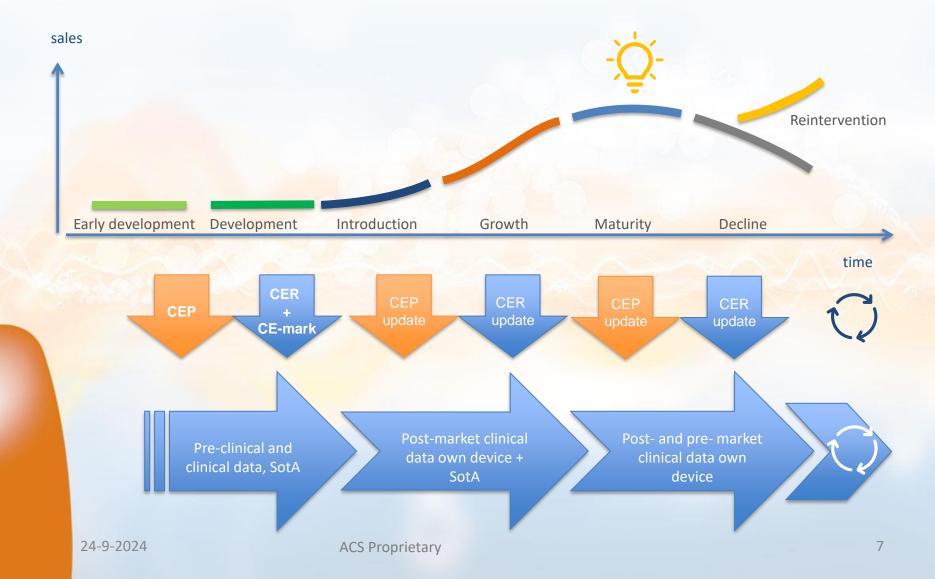
SotA (update)

- Alternative treatment
- Similar devices
- Safety / benefit
- Benchmarks

24-9-2024

Over lifetime of the device





Definitions - Clinical Studies



- Clinical Investigation (MDR)
 - Any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device
- Post-market Clinical Follow-Up (PMCF) Investigation (MDR)
 - Clinical investigation to further assess, within the scope of its intended purpose, a device which already bears the CE marking
- Pre-market clinical investigation (MDCG 2020-10)
 - Clinical investigation with non-CE marked devices, or with CE-marked devices used outside the intended use(s) covered by the CE-marking

24-9-2024 ACS Proprietary

From CEP to CER



Include in

Tech File

Clinical Investigation report (CIR)

Planning for data CEP

> Clinical Investigation Plan (CIP)

> > Setting up **EDC**

EC approval + study start

Data collection + monitoring

Literature review

Survey

Other data

24-9-2024

ACS Proprietary

Summary



- > To bring to & keep a device in the market
- Companies continuously collect data on their devices
- Data are evaluated in a clinical evaluation process
- That is planned in their clinical evaluation plan
- ➤ And "your study" is often part of their CEP

24-9-2024 ACS Proprietary 10

Where is the CEP?



If you get the question:
it should be there under MDR!

Contact the study manager: should be able get it from RA

