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

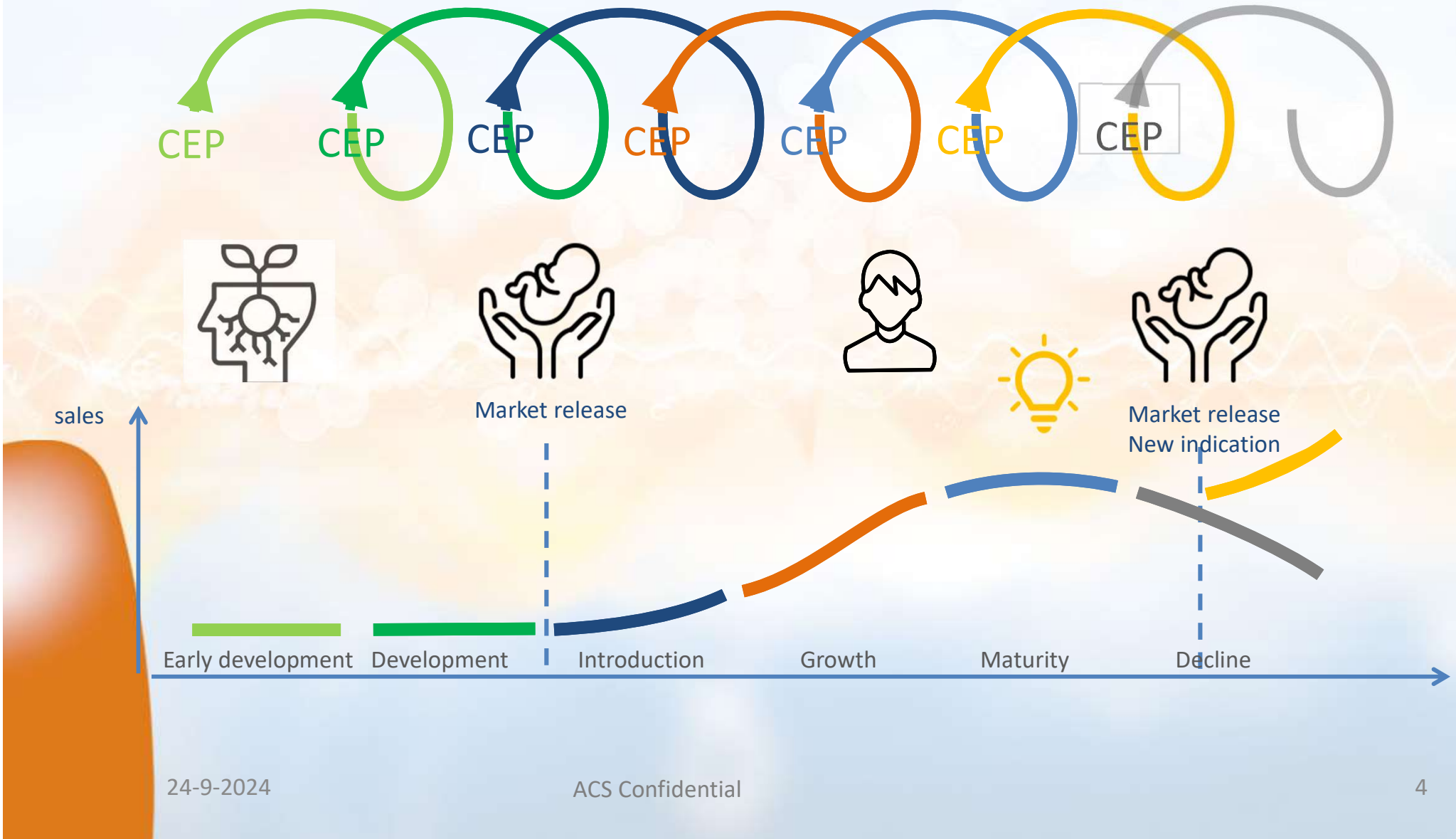
- A systematic and planned process to **continuously**

  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

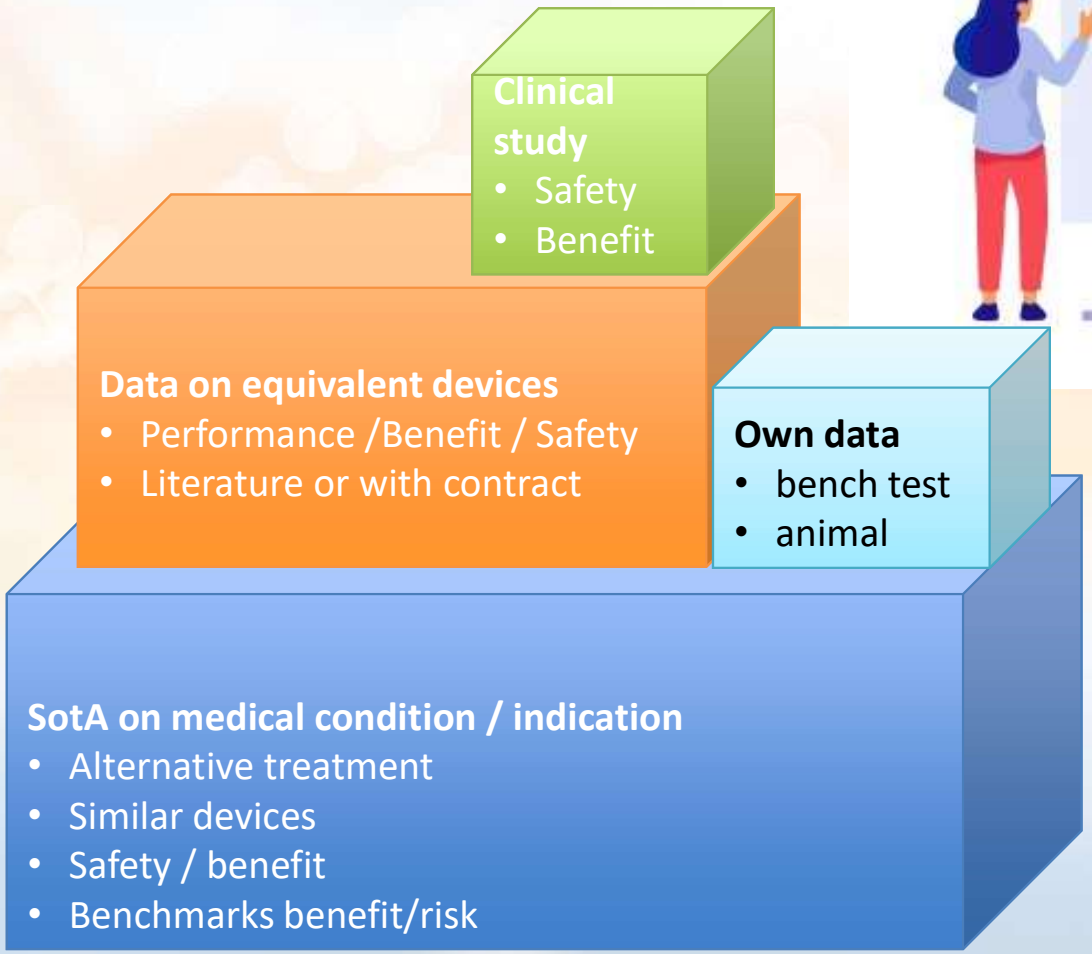
  when used as intended by the manufacturer

Over lifetime of the device



Getting a device to market

➢ Plan for clinical data in CEP



Keeping a device in market

➢ Update CEP for clinical data

Data on equivalent devices (MDD -> MDR)
- Performance / Benefit / Safety

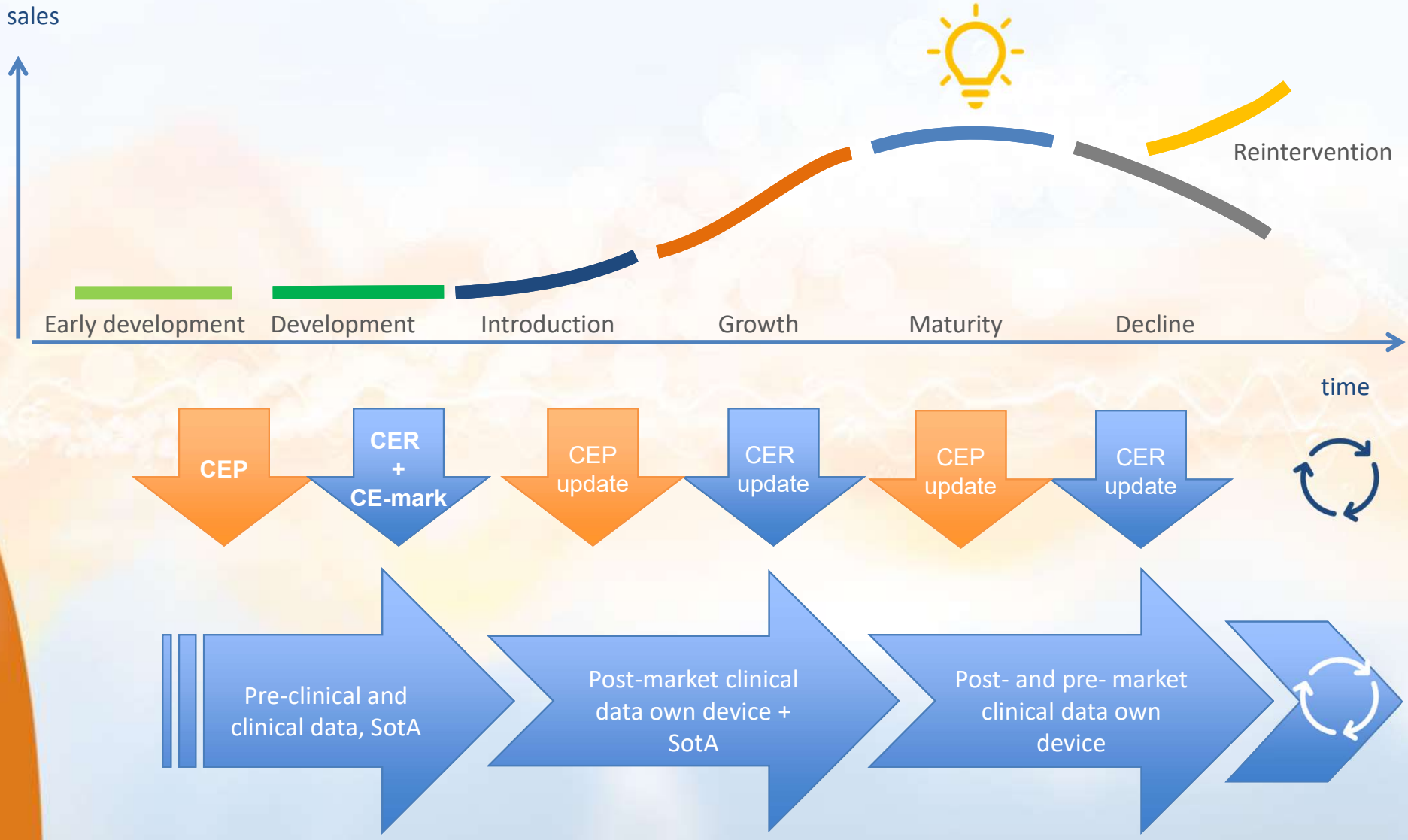
PMCF study
- Safety
- Benefit

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

PMS data
- Safety

SotA (update)
- Alternative treatment
- Similar devices
- Safety / benefit
- Benchmarks

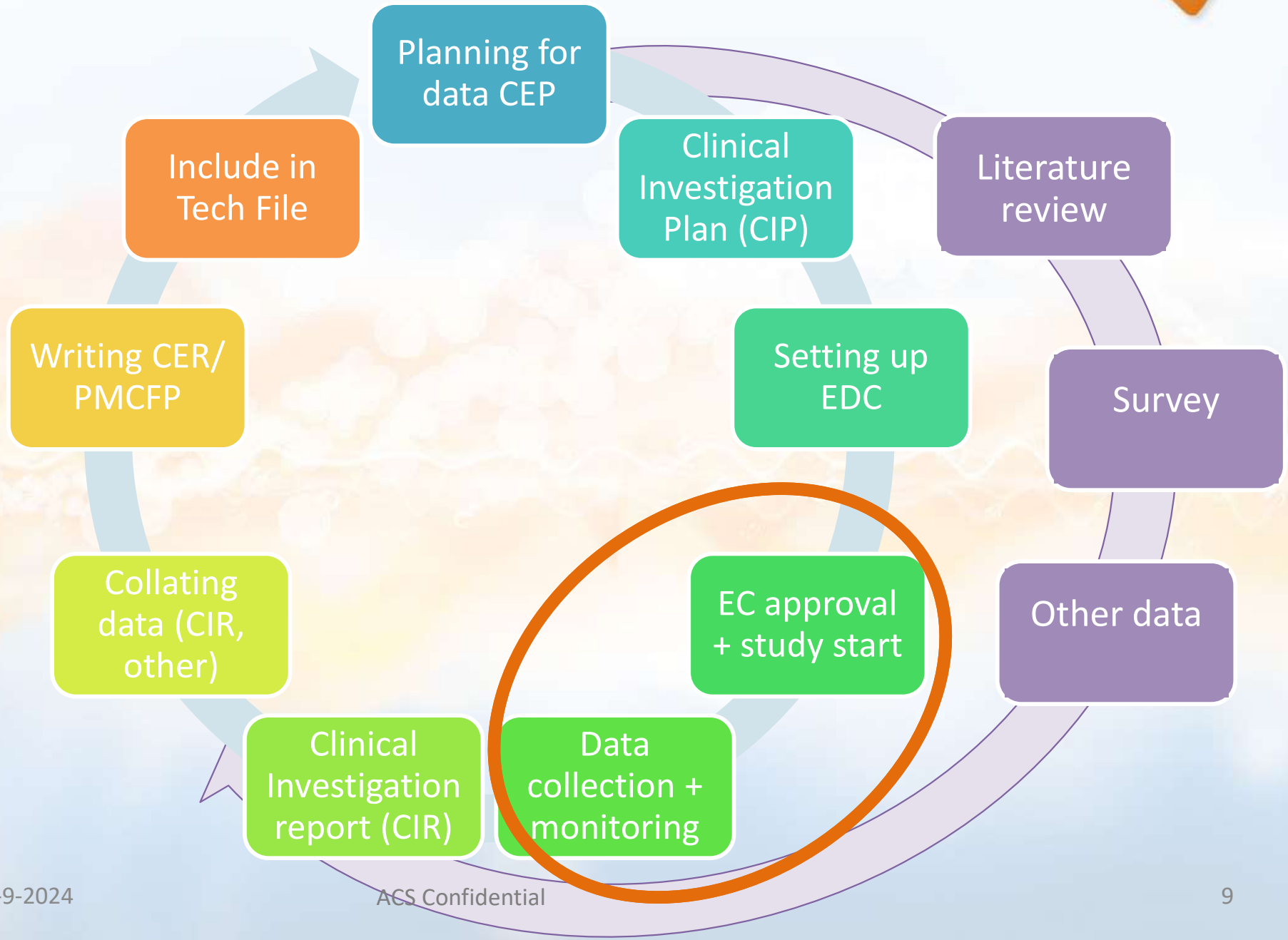
Over lifetime of the device



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

From CEP to CER



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

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