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

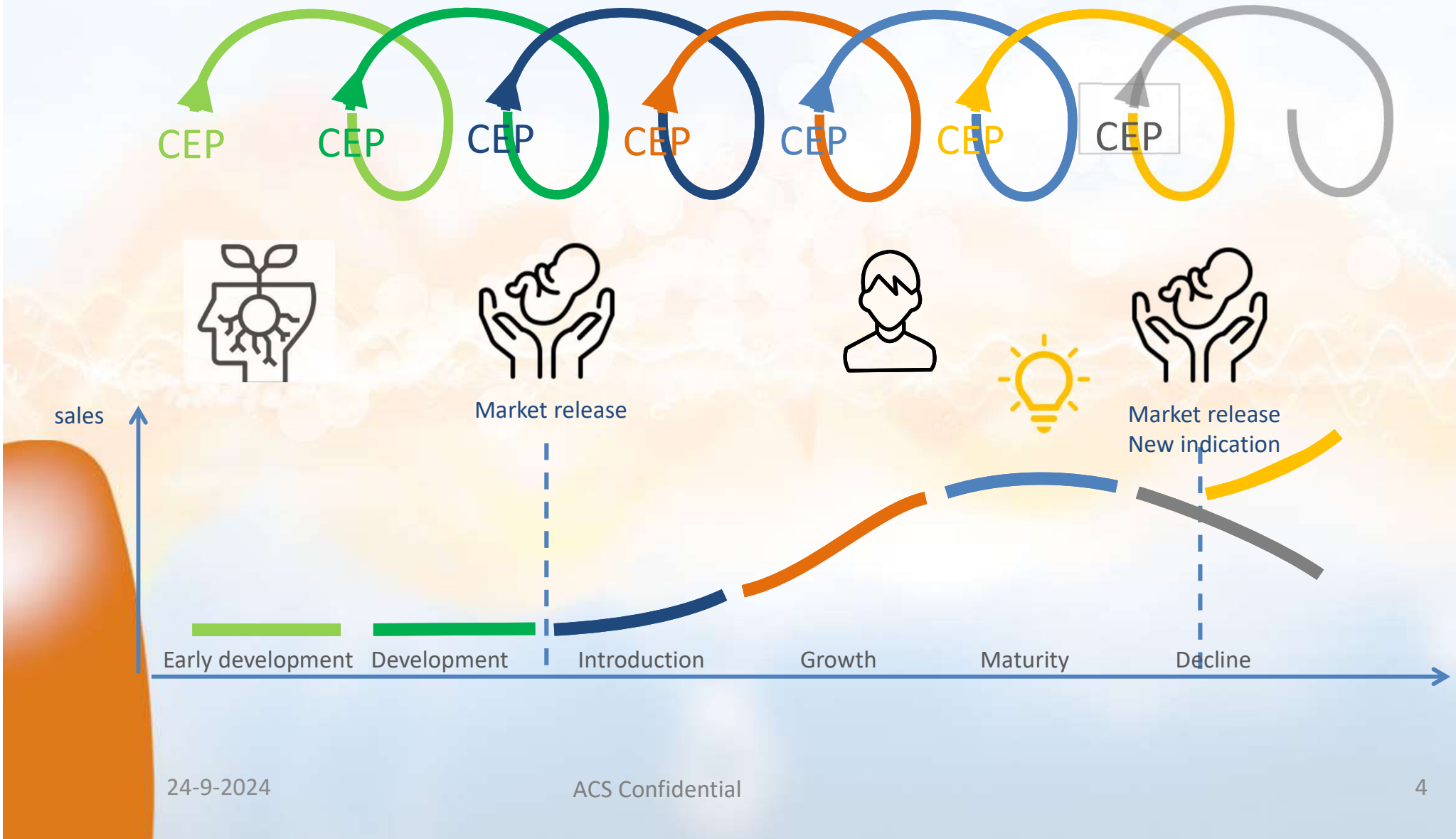
- A systematic and planned process to **continuously**

  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

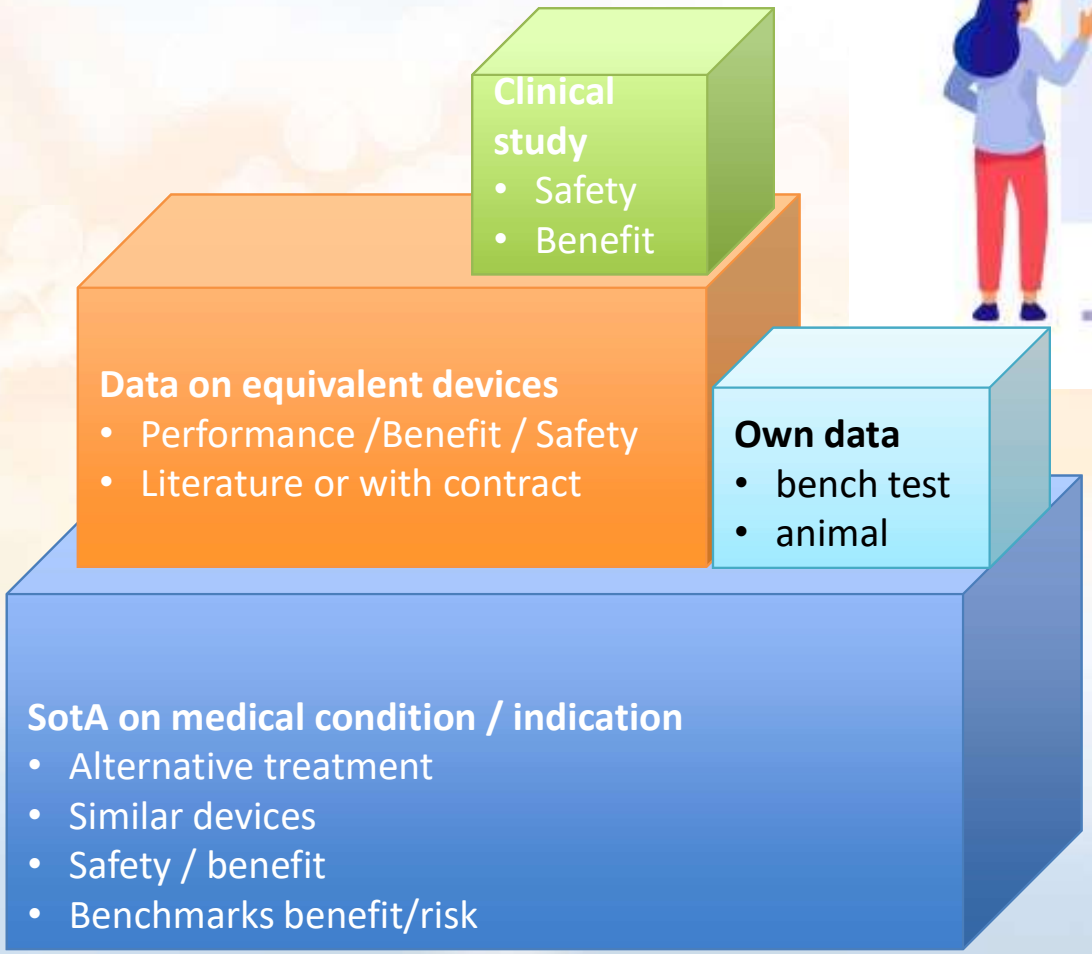
  when used as intended by the manufacturer

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

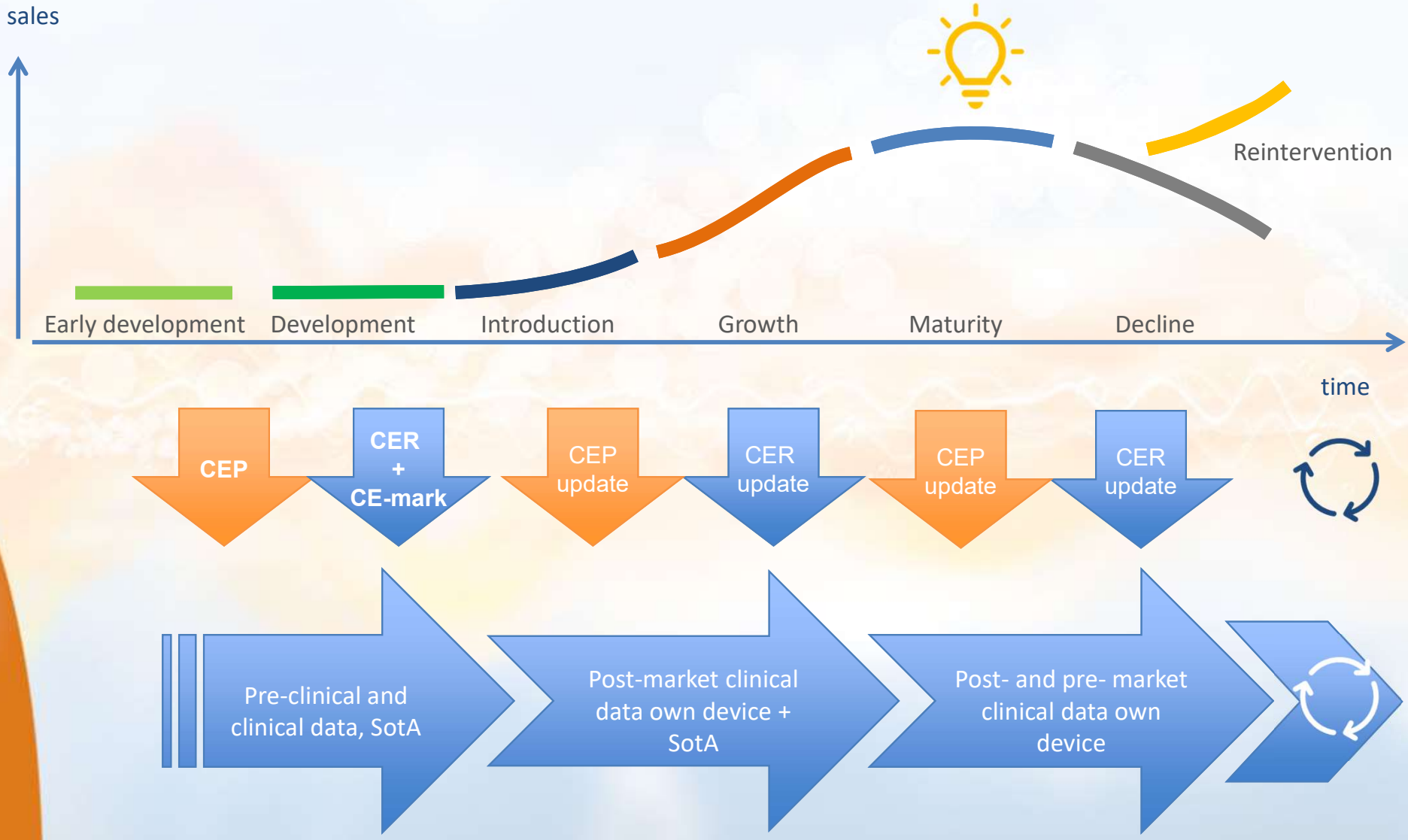
PMCF study
- Safety
- Benefit

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

PMS data
- Safety

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

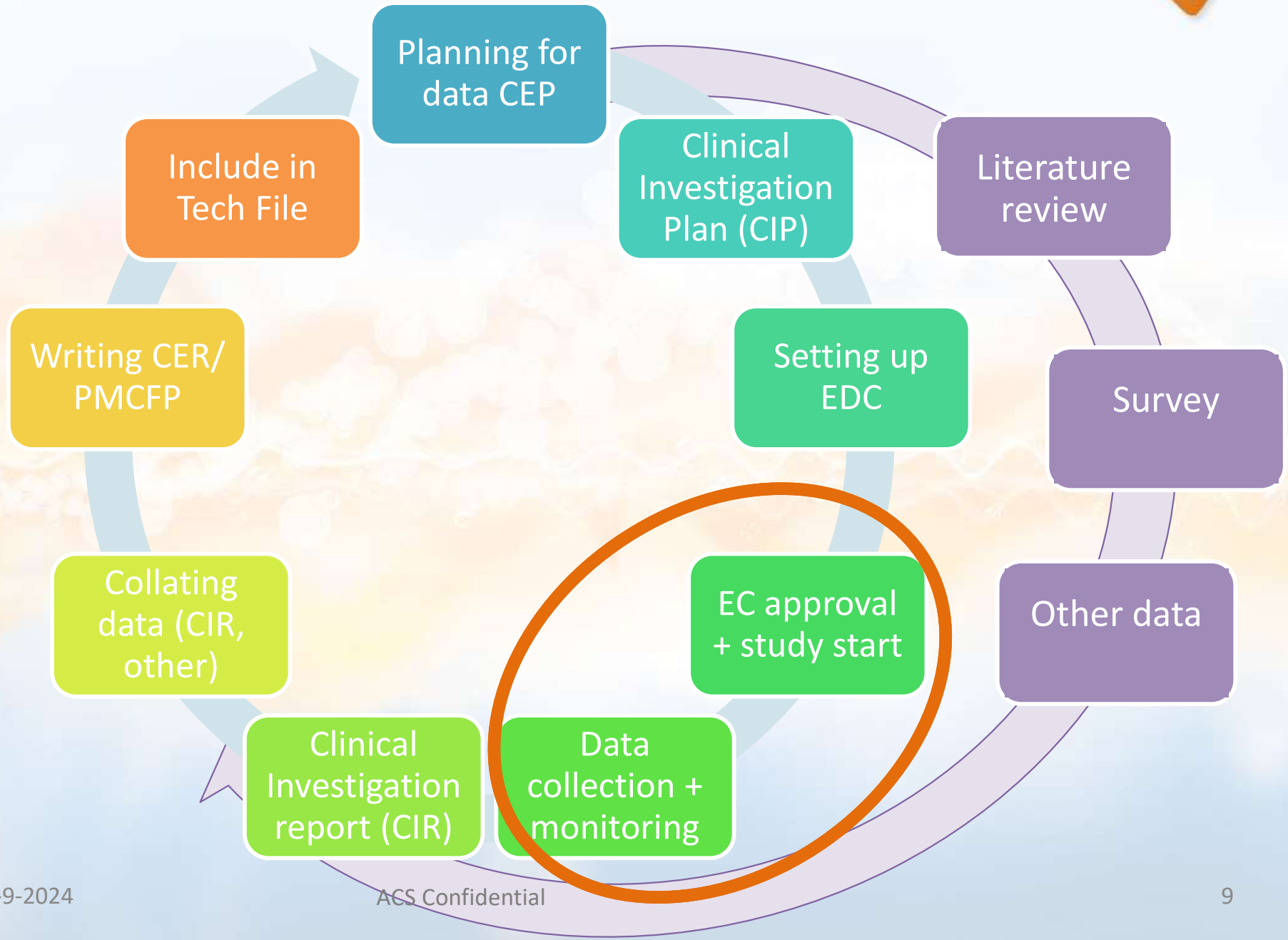
Over lifetime of the device



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

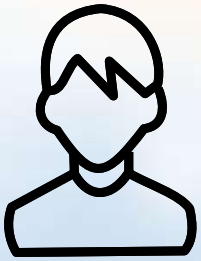
Where is the CEP?

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

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

Clinical Dev. Plan[1] (in CEP)

- From first exploratory investigations
  - First in man studies
  - Feasibility studies
  - Pilot studies
- To confirmatory studies
  - Pivotal clinical investigations
- To post- market
  - PMCF clinical data / studies



1 Clinical development plan, MDR Annex XIV, part A, art 1.

MDR on clinical investigations

- Clinical investigation for demonstration of conformity, MDR art 62
  - Suitability for intended purpose
  - Benefit / safety / side effects
- On the market, MDR art 74
  - 74.1 Invasive (burdensome) studies (PMCF)
  - 74.2 outside intended purpose (new indication)
- No conformity assessment: art 82 (other)
  - local regulations

Over lifetime of the device

First in man studies
Feasibility studies
Pilot studies
Art. 62 or Art. 82

Pivotal clinical investigation
Art 62

PMCF (art 74.1 or art 82)

New indication (Art 74.2)

Clinical Development Plan (in CEP)