IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

European Commission

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09:30 – 09:50

Post-market surveillance and RWE

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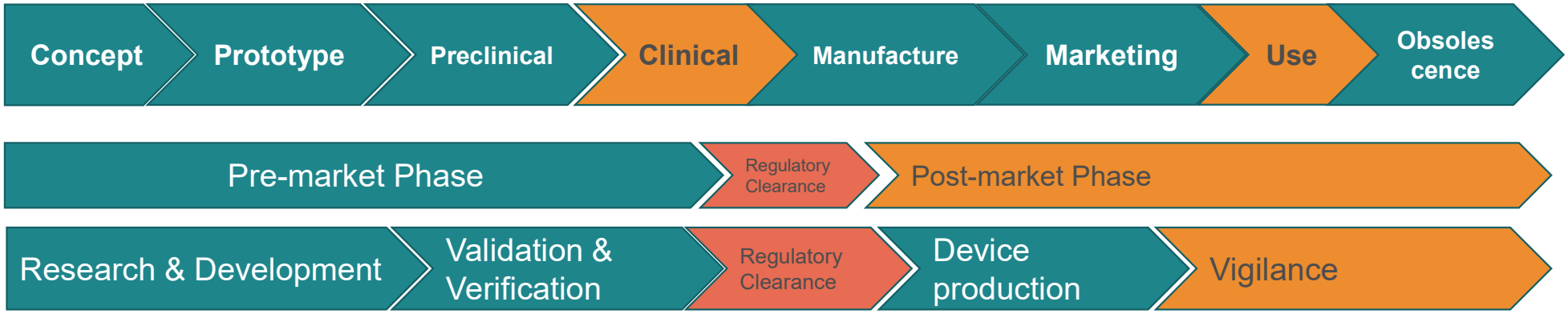
Lifecycle Approaches to Medical Devices - a short History -

IMDRF - DITTA and GMTA Joint Workshop

Dr. Matthias Neumann

DG HERA

Lifecycle Model for Medical Devices in the late 80s-mid 90s



- Not much differences to other sectors
- Post-market Surveillance (PMS) = Vigilance (sampling, reporting, assessment of serious incidents)
- Vigilance required by regulation (due to the nature of medical devices, as products effectively interacting with the human body and this interacting is causing potential risks)

- Model is working well, if there is a low level of innovation and competition

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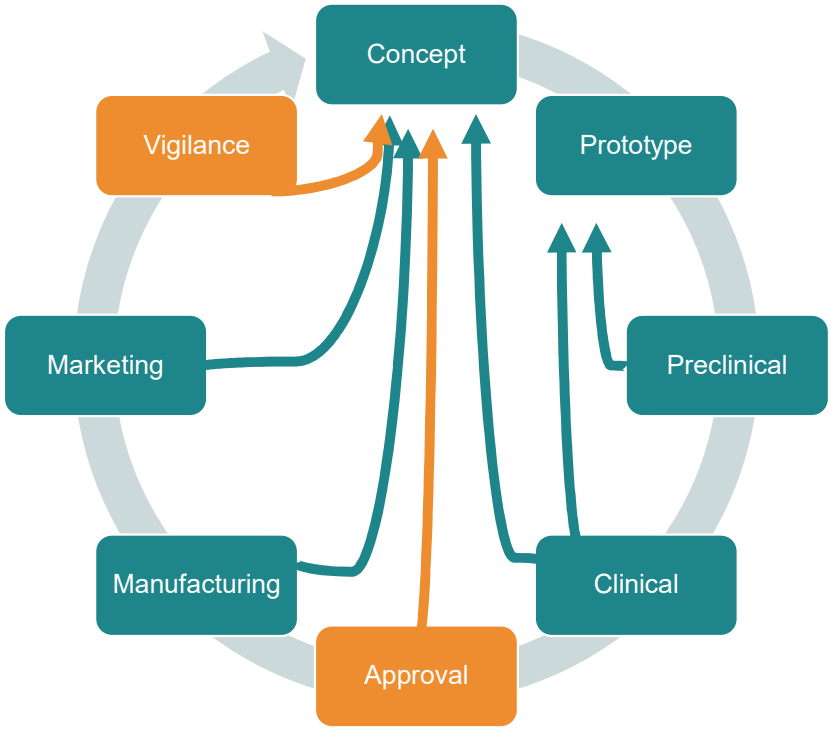
Lifecycle approaches to Medical Devices
- History -



From 1995 – 2005

- Continuous Product Improvement Concept
- Establishment of CAPA (Corrective Action/Preventive Action)
- Introduction of the Risk Management

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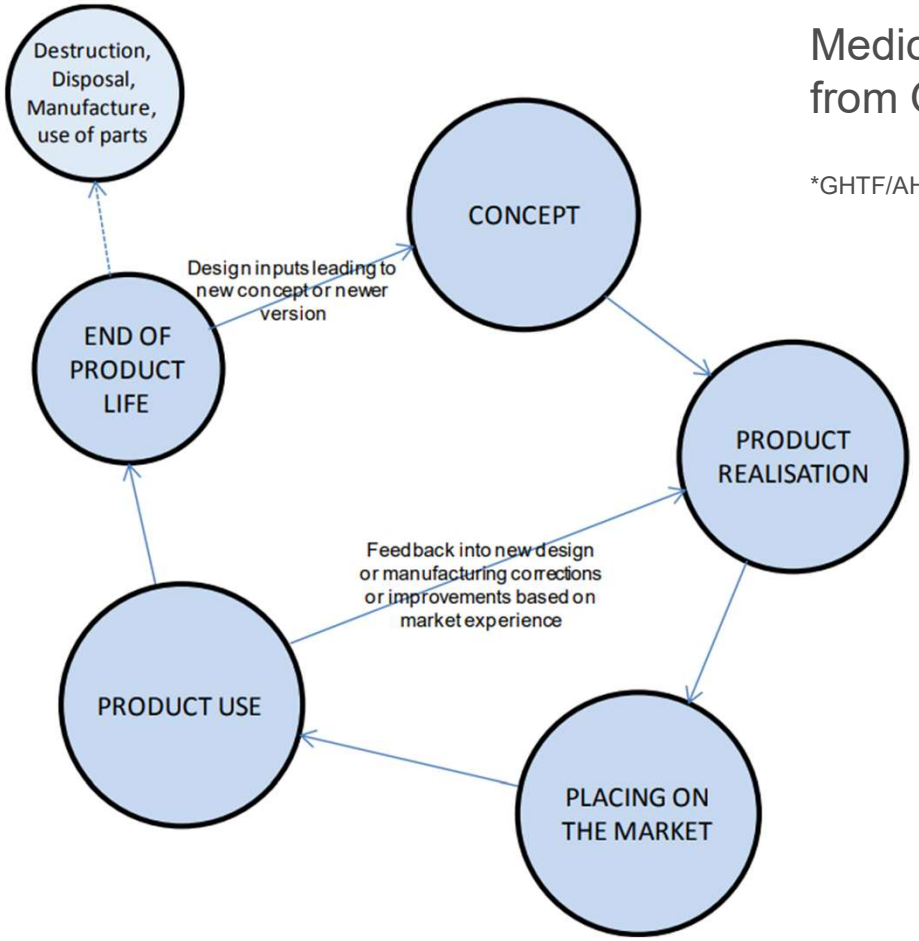
Lifecycle approaches to Medical Devices
- History -



Medical Devices Lifecycle
from GHTF Regulatory Model*

*GHTF/AHWG-GRM/N1R13:2011

From 1995 – 2010

- Continuous Product Improvement Concept
- Establishment of CAPA (Corrective Action/Preventive Action) Processes
- Introduction of the Risk Management

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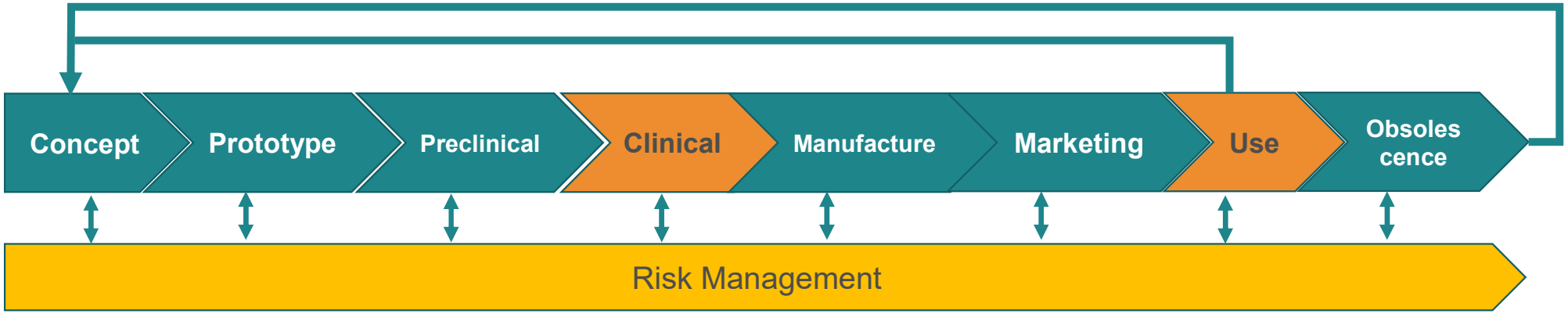
Medical Devices Lifecycle Model around 1995 - 2010



Risk management: Identify, assess and mitigate risks of a MD to ensure a positive acceptable Benefit-Risk-Ratio through the whole lifetime of a MD

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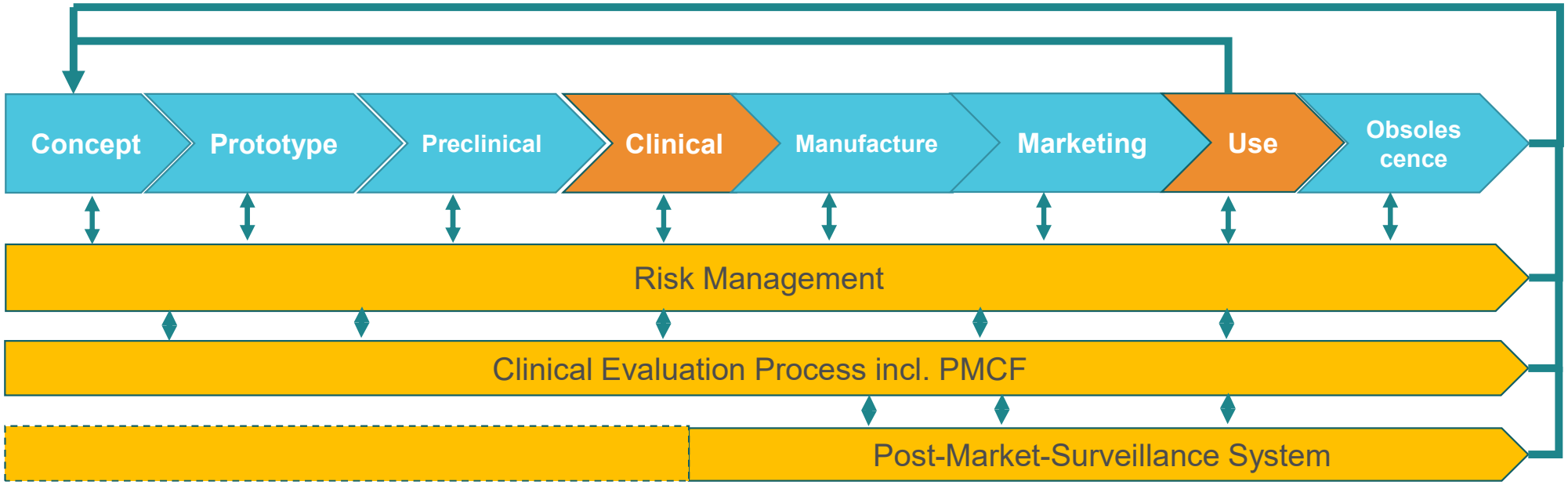
Current Medical Device Lifecycle Model



Clinical evaluation process + PMCF + PMS = Real world evidence (RWE) (“measurement” of safety and performance)

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Systematic PMS and PMCF – an opportunity for appropriate market access ?

- Ensuring a positive acceptable Benefit-Risk-Ratio of a MD through the lifetime requires “measurements” of the safety and performance in the market (RWE)
- For some MD, safety can only be ensured in the market (e.g. cybersecurity)
- Proper PMS provides also input for the next generation of MD
- In some cases (e.g. AI based MD), PMS and related RWE is essential and the main source for design input
- Proper implementation of lifecycle models based on PMS/PMCF/RWE might lead to more flexible regulatory approaches, like certificates/approvals with conditions, acceptance of new indications (based on RWE), de-novo classification,
- Special regulatory approaches for AI, Orphan Devices …

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Thank you

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Global Medical Technology Alliance
Innovating for a Healthier World

IMDRF - DITTA and GMTA Joint Workshop Agenda

The life cycle of medical devices: The importance of post-market-related activities

Lifecycle approach to medical devices (scene setter)

Philippe Auclair

March 27, 2023

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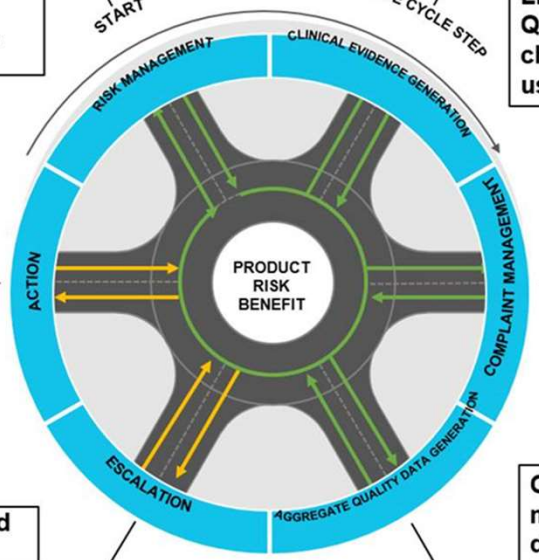
Device Life cycle

Post Market Surveillance System

Support for product risk classification, risk management process, benefit risk determination, PMS planning

CAPA, Field Safety Corrective Action, Field Safety Notice

Quality and safety signals, threshold updates



Source of Human Clinical Data, Literature Search, Post Market Quality Data, size and other characteristics of the population using the device

Complaints, Adverse Events, Serious Incidents (MIR, PSR), PMCF, undesirable side-effects; feedback from users, distributors and importers

Complaint Trending, Trend Report, medical or technical literature, databases and/or registers, PMCF Report, sales data

Image 1: Data source feeds to be used for the generation of the Reports

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New Technologies

SAMD- AI

- Challenges posed by Software- Artificial intelligence
  - Rapid innovation iteration . communication vs FSCA
  - New data feed to be defined . eg Consumers , focus groups ; Real World Evidence ……
- Need harmonization , pooling data
  - Reliance on IMDRF Adverse Event Terminology

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GMTA's message

*"The future of medical products regulation is in convergence/harmonization, collaboration, and networking based on **reliance** and trust."*