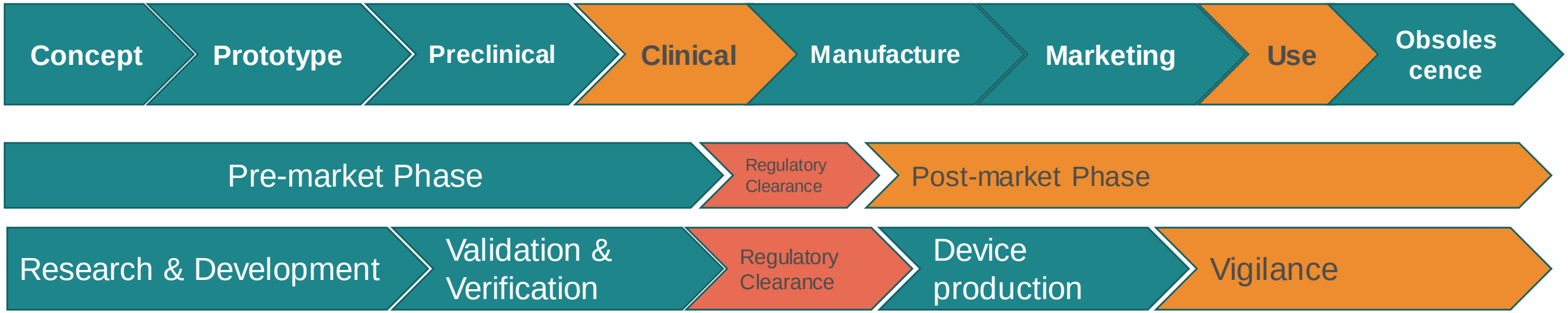
Lifecycle Approaches to Medical Devices - a short History -

IMDRF - DITTA and GMTA Joint Workshop

Dr. Matthias Neumann

DG HERA

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

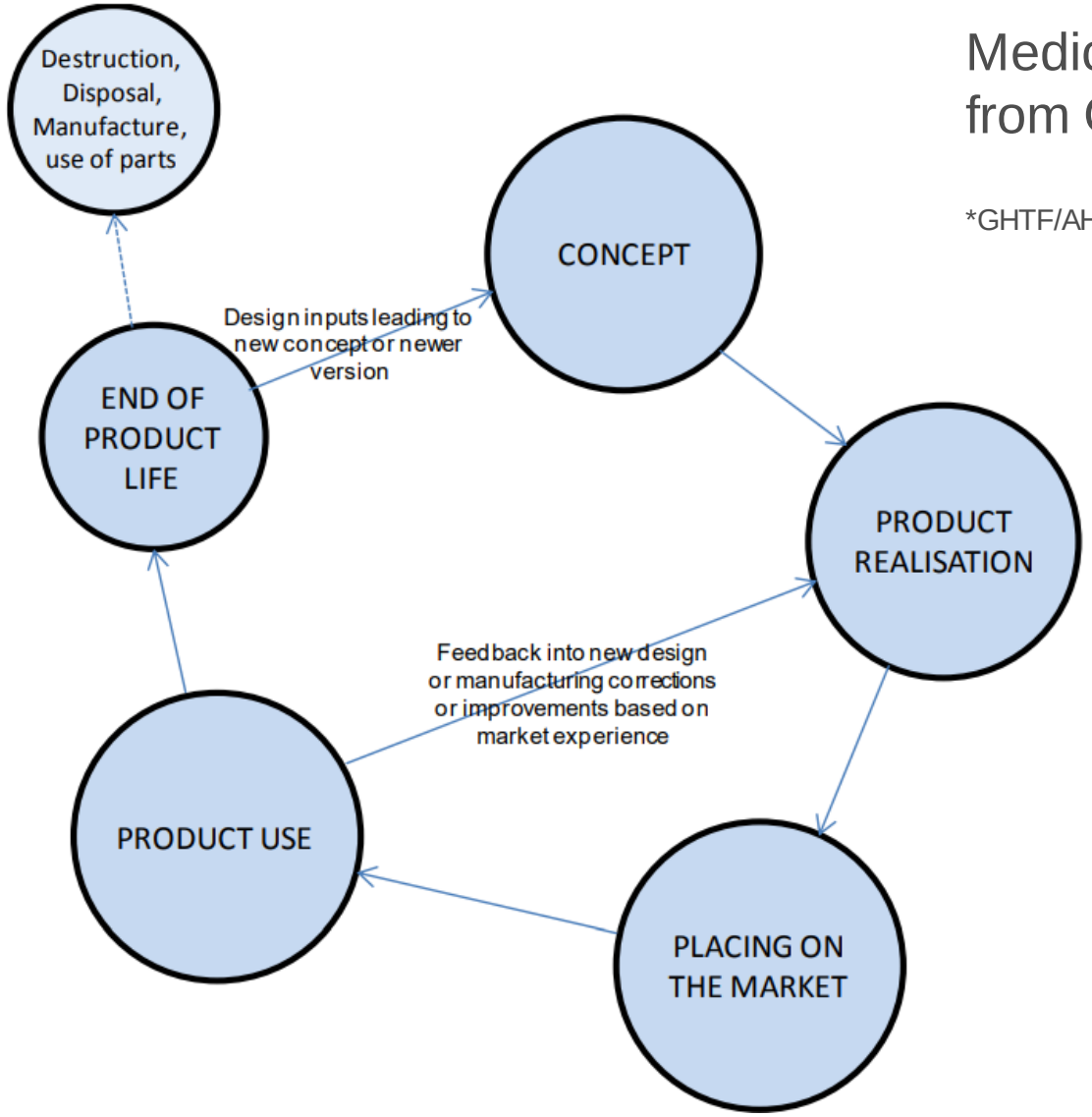


- Not much differences to other sectors
- Post-market Surveillance (PMS) = Vigilance (sampling, reporting, assessment of serious incidents)
- Vigilance required by regulation (due to the nature of medical devices, as products effectively interacting with the human body and this interacting is causing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

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

European Commission

Lifecycle approaches to Medical Devices
- History -



Medical Devices Lifecycle
from GHTF Regulatory Model*

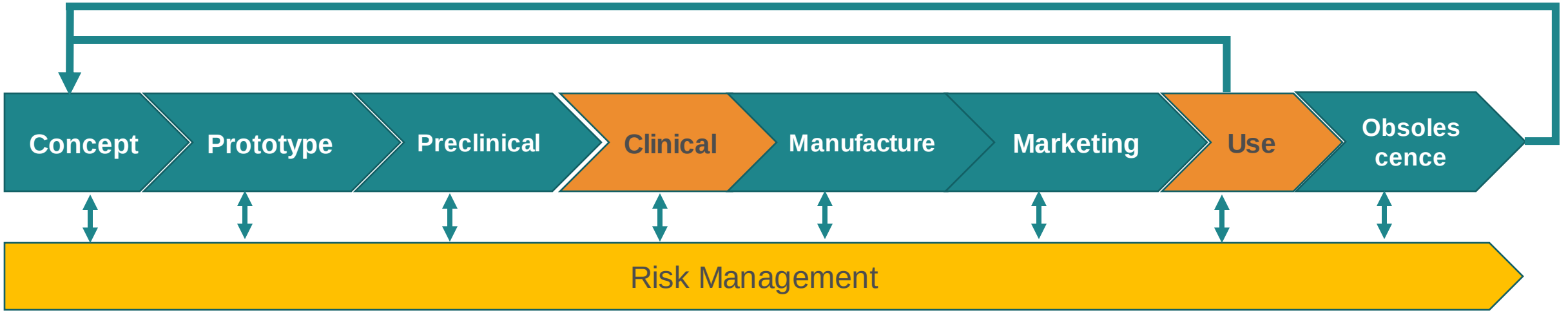
*GHTF/AHWG-GRM/N1R13:2011

From 1995 – 2010

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

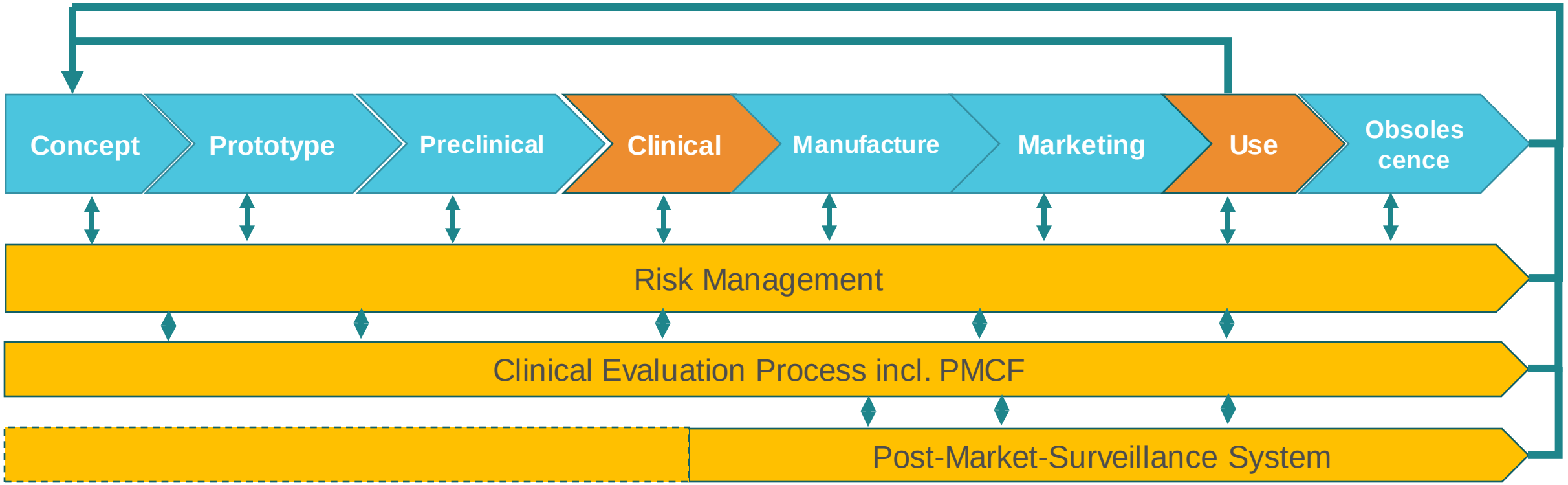
European Commission

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

Current Medical Device Lifecycle Model



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

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 …

Thank you

Dr. Matthias Neumann
Policy Officer - Medical Counter-Measures

Health Emergency Preparedness and Response Authority
HERA.3

L-15 02 P003- 15 RUE DE LA LOI

B-1049 Brussels/Belgium
+32 229-94616
matthias.neumann@ec.europa.eu

European Commission