

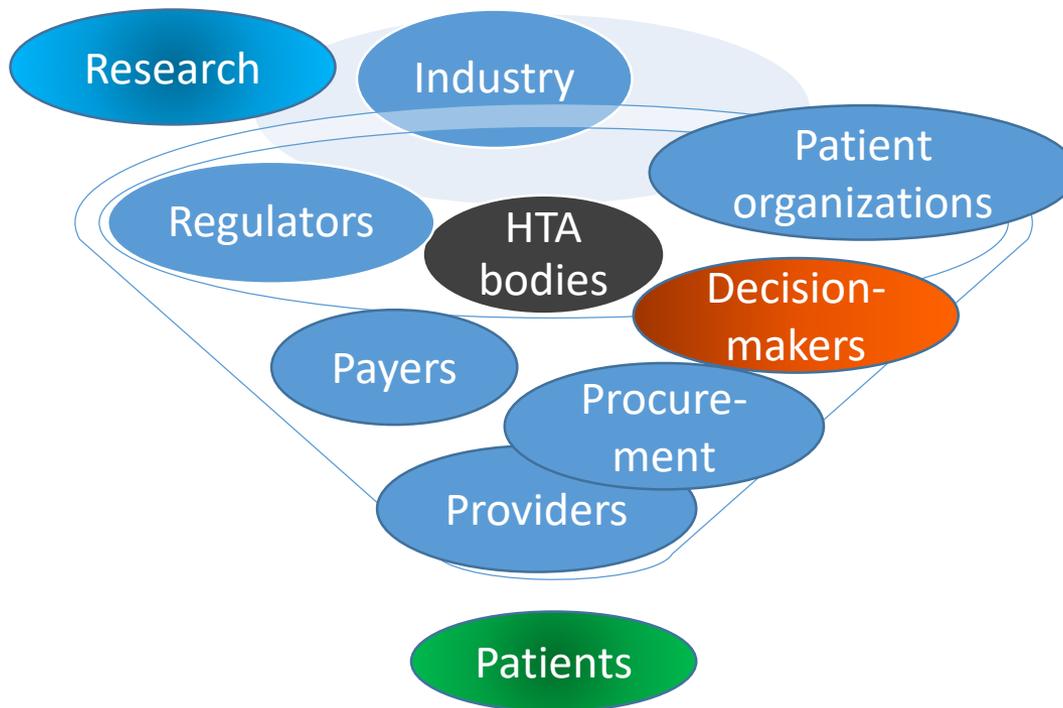
# IP7: CHANGING PARADIGM IN THE EVALUATION OF THE VALUE OF MEDICAL DEVICES: WHAT MUST STAKEHOLDERS EXPECT IN THE NEW DECADE?

*Department director Øyvind Melien*

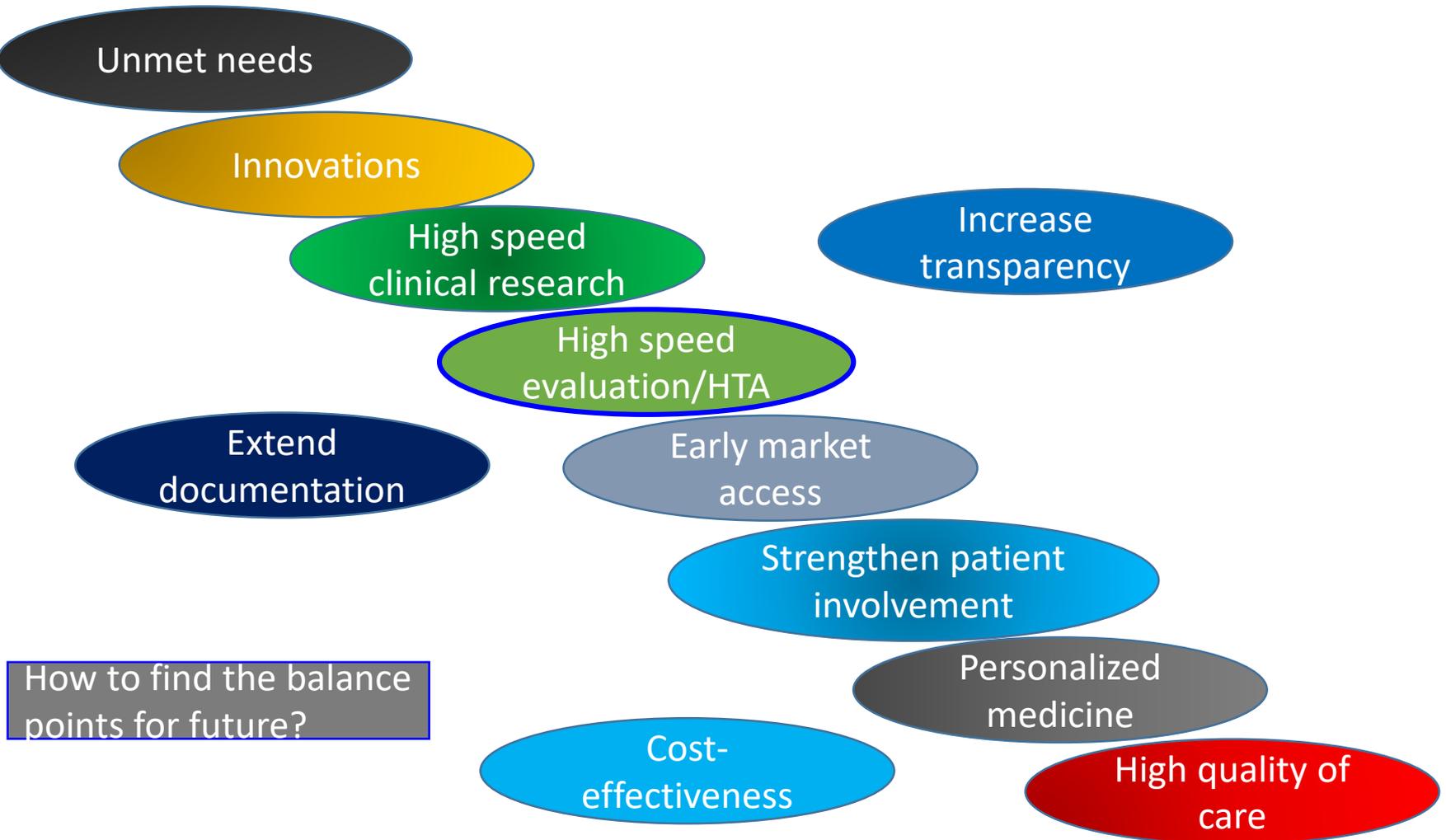
*Assessment interventions, Norwegian Institute of Public Health (NIPH)*

BREAKOUT SESSION 2  
Monday, November 12, 2018  
15:45 - 16:45

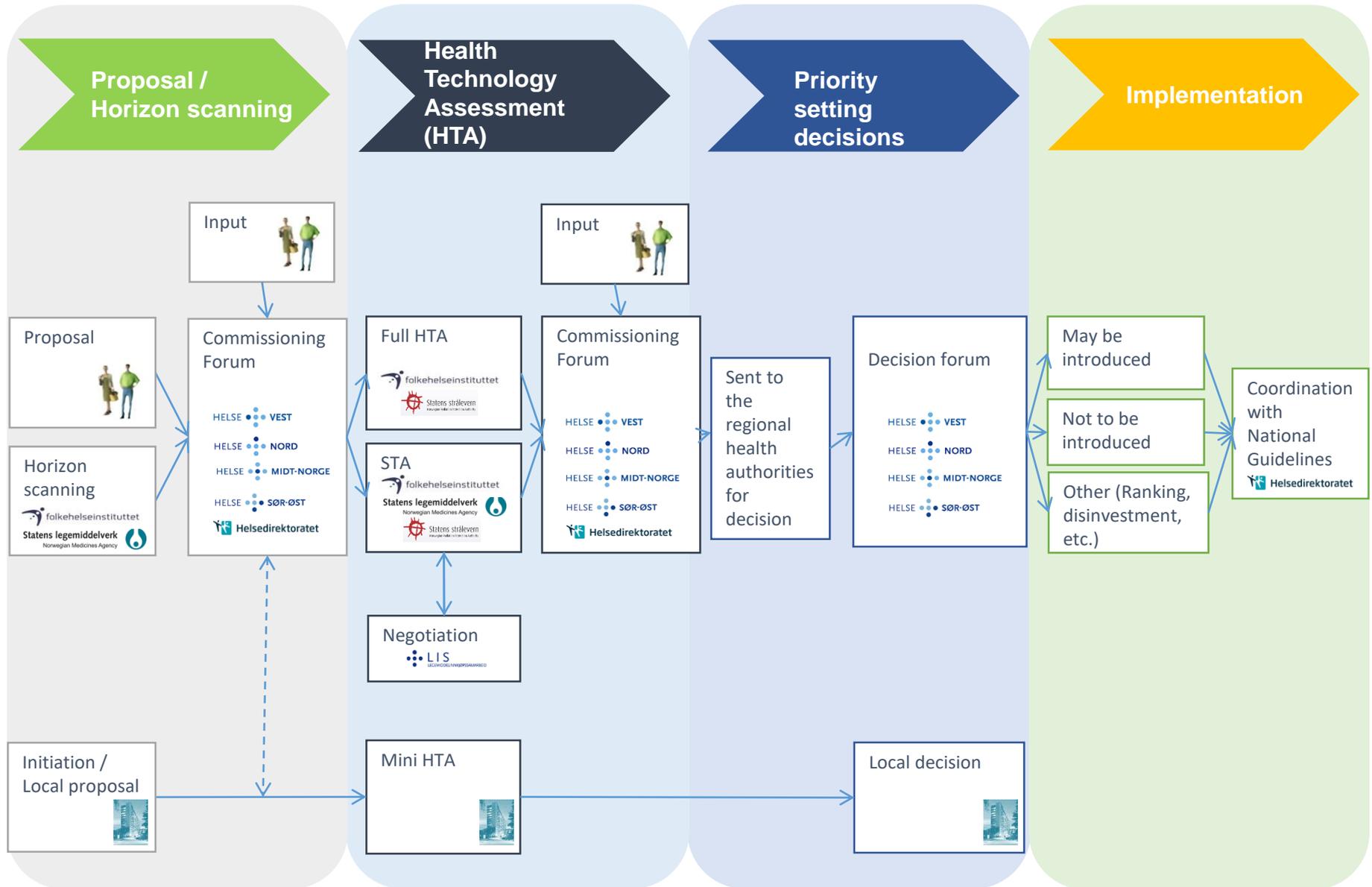
# Changing landscape - changing paradigms



# Expectations - Driving forces -Trends



# Example from Norway: Present model HTA processes



# The needs for patients and healthcare

**Given limited resources and budgets an increased focus on fundamental and unmet needs is likely to be expected to guide areas and technologies for evaluation**

- *Further development/refinement of instruments for selection of topics*
  - *Prioritization criteria (e.g. severity of disease) corresponding to criteria for healthcare in general*
- *The future impact of **personalized medicine** may expand the understanding of unmet needs both at individual and system level*

# Need to strengthen the life cycle perspective

Need to build a framework supporting a **life cycle perspective** for medical technologies

- *significant interest for the launch phase*
- *in the future a need to extend and strengthen focus on prelaunch and postlaunch phases*
  - e.g. - *what are the unmet needs?*
  - *what are the outcomes, values in clinical practice?*

Development  
of technology

Prelaunch

Launch

Postlaunch

*Life cycle perspective*

# Need to improve and extend data collection

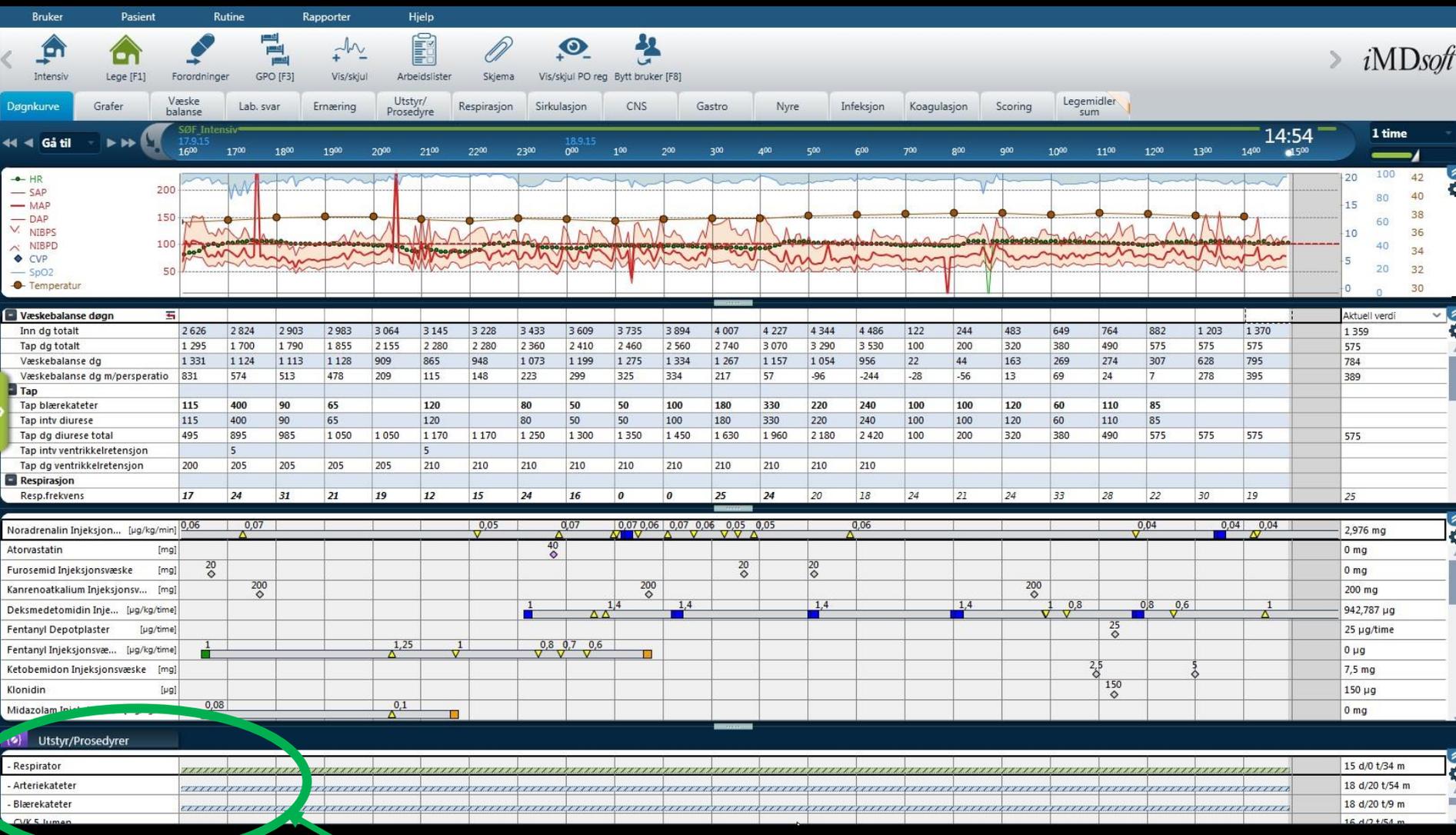
**Need to improve and extend the data platform for evaluation to correspond to the life cycle of medical technologies allowing for assessments and reassessments of value including**

**Clinical research data**

**Health data**

**Patient experiences**

# Novel instrument for collecting data from health care: electronic patient curve systems (Intensive care unit, Norway)



Medical technologies/procedures

With permission: Harald Noddeland, OUS

# Need to build frameworks for more efficient data-sharing throughout the lifecycle of technologies



International

CRIGH

HTAi  
INAHTA

GIN

Europe

ECRIN

EUnetHTA

European  
Guidelines

Nordic  
countries

Nordic Trial  
Alliance

Nordic  
collaboration

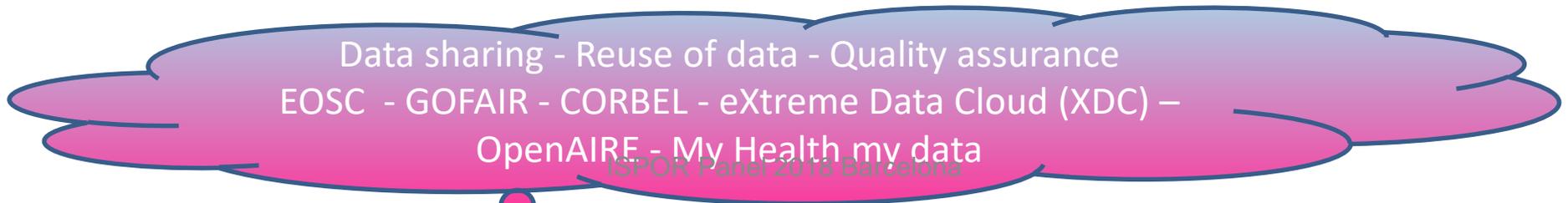
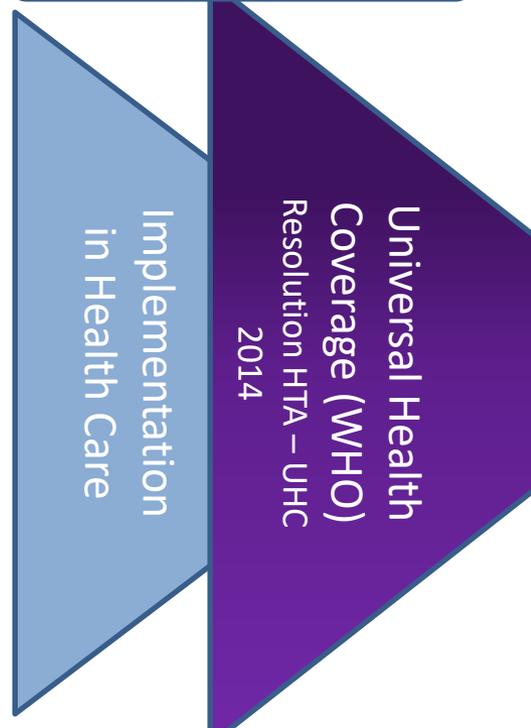
GIN Nordic

Norway

NORCRIN

«Nye metoder»

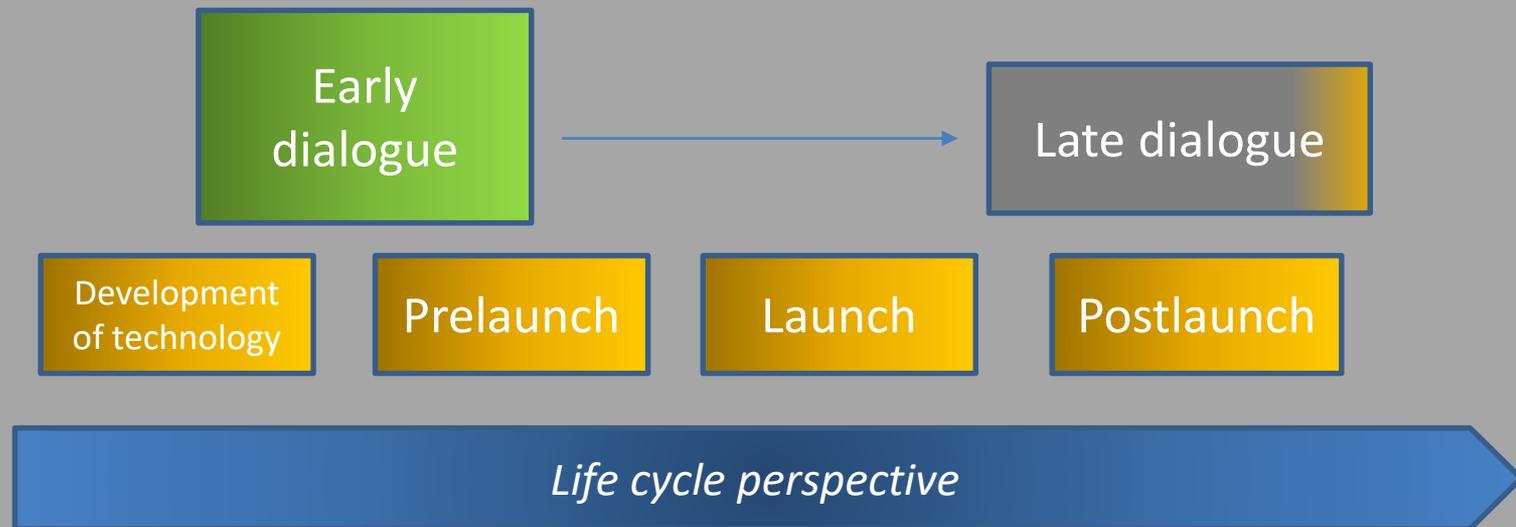
National  
Guidelines



# Need for broader involvement and dialogue throughout the life cycle

Strengthen dialogue between industry, regulatory authorities, HTA bodies, payers, patient representatives and other stakeholders from an early stage

Clarify needs for data both for regulatory and HTA processes



Ongoing project

## International Initiatives on the Assessment of the Value of Medical Technologies

- **Objective:**
  - Identify the current role of HTA; and other tools/ approaches/methods used to assess the value of medical technologies globally and locally; and develop reflections for a future role that HTA could have in assessing medical technologies throughout their lifecycle to inform decisions and healthcare policies.
- **Recommendation:**
  - There is a need to explore more closely how to utilize and adapt HTA as a supportive tool in the life cycle of medical technologies to benefit patients, health systems and society, and consider the value of other tools and initiatives on novel value frameworks to inform decisions and reach policy objectives.