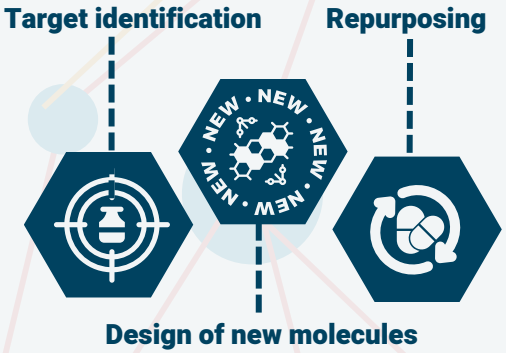
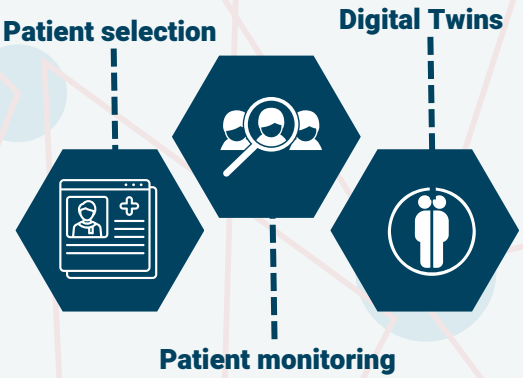
# FOUR MAIN USES OF AI IN MEDICINES R&D AND SPECIFIC RISKS

## AI IN MEDICINE DISCOVERY



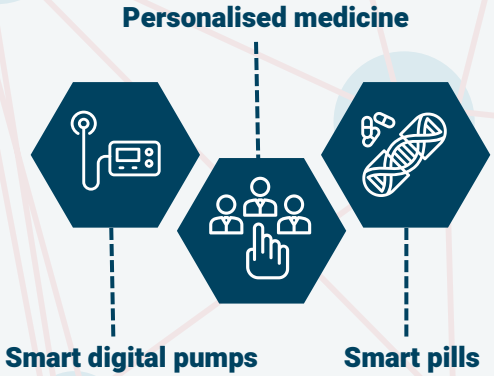

Mostly positive use cases with few specific risks.

## AI IN CLINICAL TRIALS




Specific risks that relate to informed consent, the quality of evidence and validation of the AI methods used.

## AI IN PHARMACEUTICAL PRODUCTS




Specific risks that relate to patient safety, AI liability, discrimination and black-box decision making.

## AI IN PHARMACEUTICAL PROMOTION


Fundamentally controversial, leads to higher sales instead of healthier patients.

# REGULATORY FRAMEWORK

### EU MEDICAL DEVICES REGULATION

Sets out requirements for all medical devices, including AI assisted medical devices.

No specific AI requirements

### EU CLINICAL TRIALS REGULATION

Sets out standards for clinical trial conduct and patient participation, including for CTs using AI systems.

No specific AI requirements

### EU MEDICINAL PRODUCTS REGULATION

Sets out rules governing development, approval and use of medicines in Europe.

No specific AI requirements

### EU ARTIFICIAL INTELLIGENCE ACT

Regulates AI-assisted medical devices, but does not regulate AI used in pharmaceutical R&D.

Few AI systems regulated

### EU GENERAL DATA PROTECTION REGULATION

Regulates all uses of data in the EU, including uses by AI systems.

Regulates all data uses

**Besides specific risks, Artificial Intelligence always carries general risks relating to bias and discrimination, privacy and cybersecurity.**