

Preclinical development

Offline validation<sup>§</sup>

Safety/utility,  
small-scale

Safety/effectiveness,  
large-scale

Post-market surveillance

## Drugs

preclinical trials

clinical trials  
phase 1

clinical trials  
phase 2

clinical trials  
phase 3

pharmacovigilance  
phase 4

## SPIRIT/CONSORT(-AI)

## AI in healthcare

### TRIPOD-AI & STARD-AI

*in silico*  
evaluation

*silent/shadow*  
evaluation

### DECIDE-AI

*early live clinical*  
evaluation

comparative  
prospective evaluation

vigilance

## Surgical innovation

### IDEAL

IDEAL stage 0

IDEAL  
stage 1

IDEAL  
stage 2a

IDEAL  
stage 2b

IDEAL stage 3

IDEAL stage 4