AIIC 2024 ROMA

GESTIRE L'INNOVAZIONE

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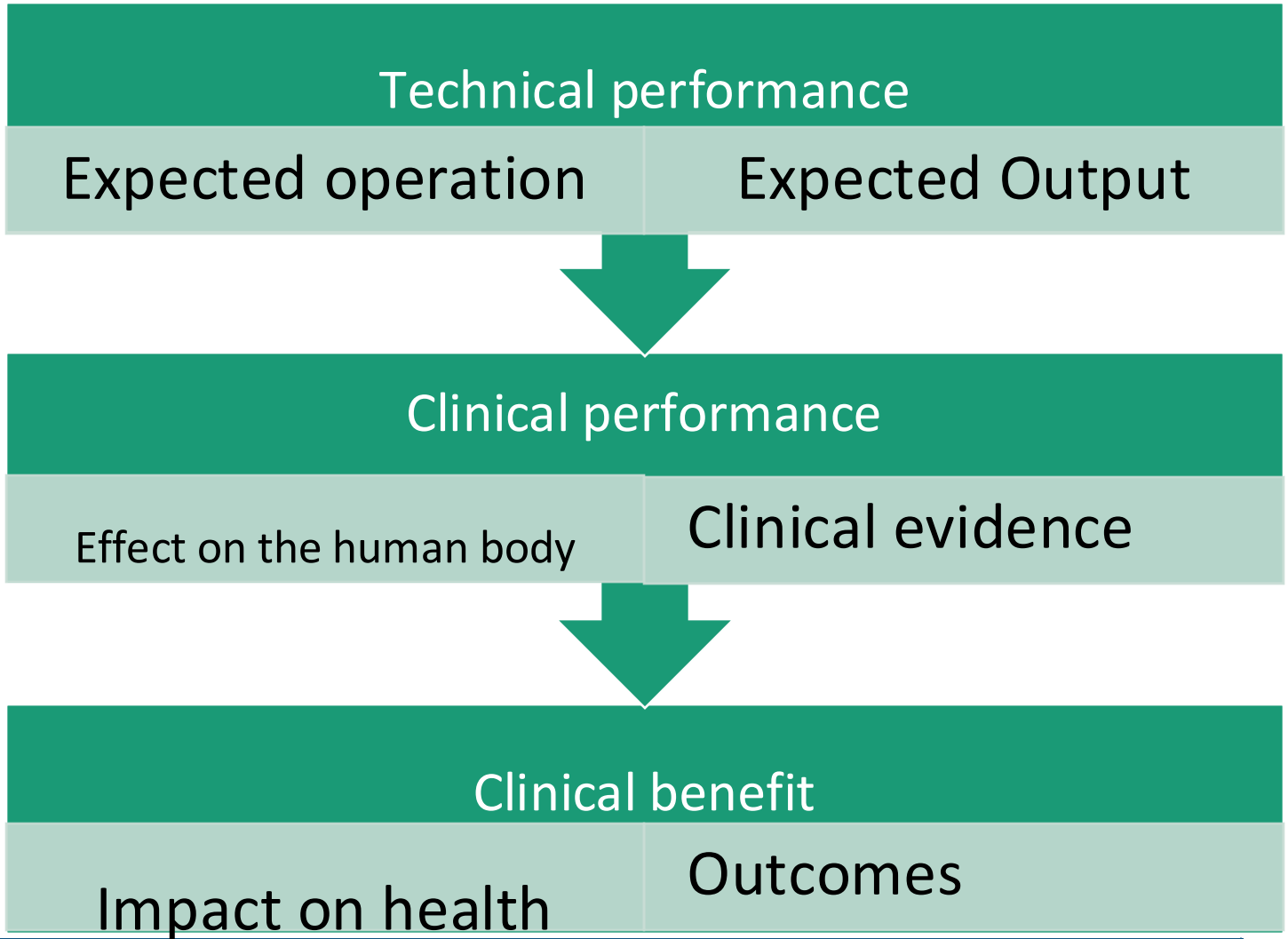
MISURE A SOSTEGNO DELL'INNOVAZIONE

Articolo 53 Sandbox normative sull'IA

Le autorità nazionali competenti possono istituire sandbox regolamentari per l'IA per lo sviluppo, la formazione, il collaudo e la convalida di sistemi innovativi di IA sotto la diretta supervisione, guida e supporto dell'autorità nazionale competente, prima che tali sistemi siano immessi sul mercato o messi in servizio. Tali sandbox regolamentari possono includere test in condizioni reali supervisionati dalle autorità nazionali competenti.

Articolo 54
Ulteriore trattamento dei dati personali per lo sviluppo di determinati sistemi di IA nell'interesse pubblico nella sandbox normativa sull'IA

1. Nella sandbox normativa sull'IA i dati personali legittimamente raccolti per altre finalità possono essere trattati ai fini dello sviluppo, della sperimentazione e della formazione di sistemi innovativi di IA nella sandbox alle seguenti condizioni


Technical performance
Expected operation
Expected Output
Clinical performance
Effect on the human body
Clinical evidence
Clinical benefit
Impact on health
Outcomes

Benefits

- positive **impact on clinical outcome** (such as reduced probability of adverse outcomes, e.g. mortality, morbidity; or improvement of impaired body function),
- the patient's **quality of life** (significant improvements, including by simplifying care or improving the clinical management of patients, improving body functions, providing relief from symptoms),
- outcomes related **to diagnosis** (such as allowing a correct diagnosis to be made, provide earlier diagnosis of diseases or specifics of diseases, or identify patients more likely to respond to a given therapy),
- positive impact from diagnostic devices on clinical outcomes, or
- **public health impact** (such as to the ability of a diagnostic medical device to identify a specific disease and therefore prevent its spread, to identify phases, stages, location, severity or variants of disease, predict future disease onset).

Describing the clinical benefit of a therapeutic device

positive impact on clinical outcome

- reduced probability of adverse outcomes AS mortality, morbidity
- improvement of impaired body function

patient's quality of life

- significant improvements, including by simplifying care
- improving the clinical management of patients
- improving body functions
- providing relief from symptoms

specific medical purposes:
—treatment or alleviation of disease,
—treatment, alleviation of, or compensation for, an injury or disability,
—replacement or modification of the anatomy or of a physiological or pathological process or state,

Describing the clinical benefit of a monitoring or diagnostic device

outcomes related to diagnosis

- allowing a correct diagnosis to be made,
- provide earlier diagnosis of diseases or specifics of diseases,
- identify patients more likely to respond to a given therapy

positive impact from diagnostic devices on clinical outcomes

public health impact

- the ability of a diagnostic medical device to identify a specific disease and therefore prevent its spread
- to identify phases, stages, location, severity or variants of disease,
- predict future disease onset

specific medical purposes:
— diagnosis, prevention, monitoring of disease,
— diagnosis, monitoring, of an injury or disability,
— investigation of the anatomy or of a physiological or pathological process or state,
— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

Clinical benefit: evidence based medicine

PILOT

- TECHNOLOGY VALIDATION
- Confirmation of valid clinical association
- Significance of clinical parameters
- Pre-sets of technology or degrees of autonomy
- Usability in real life

PIVOTAL

- Statistically significant
- Dedicated design for regulatory compliance
- Performance, benefit and safety endpoints

dataset

POST MARKET

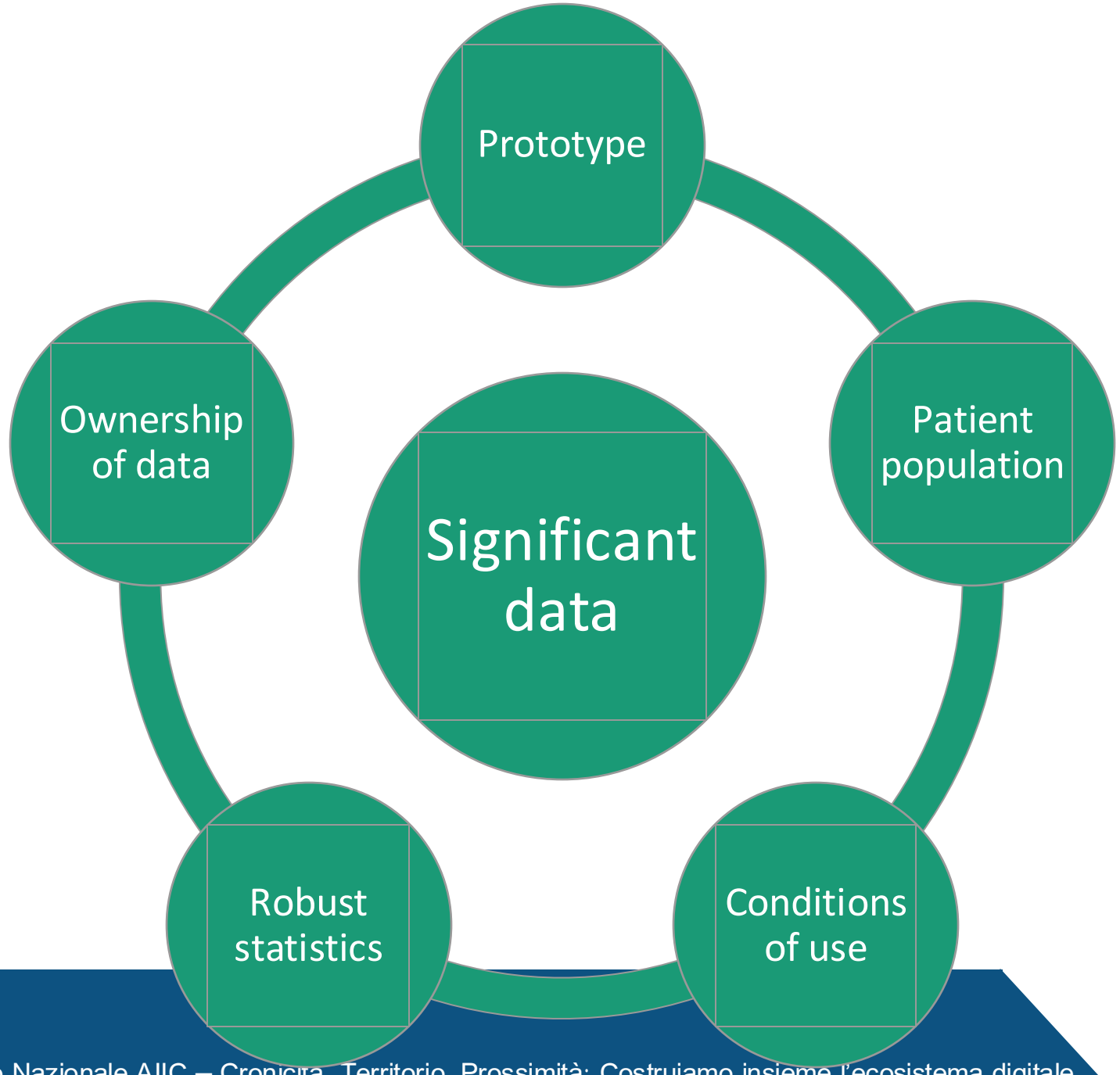
- Surveillance
- Confirmation of risk probability in larger populations
- Change control

Aim of the clinical evaluation

Give proof

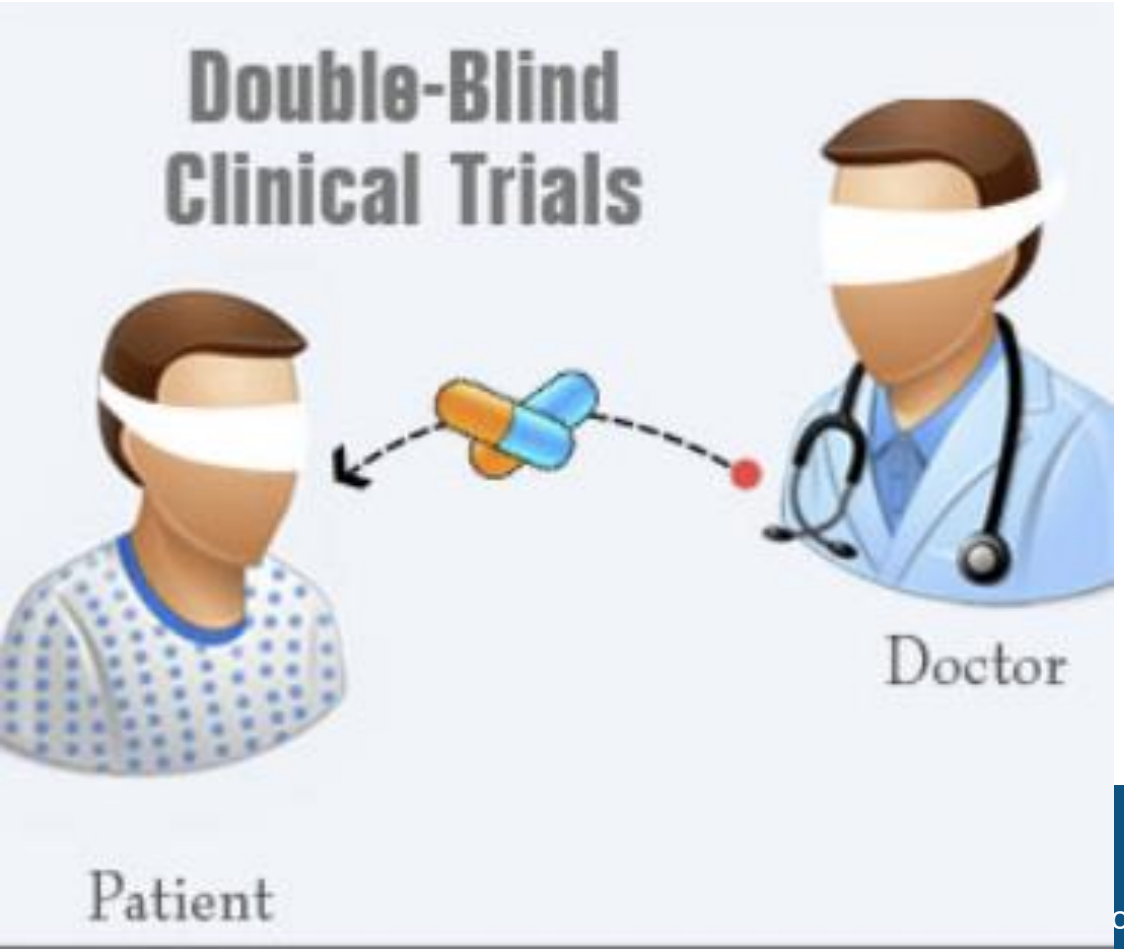
- Conformity to applicable Essential Requirements
- Safety
- Clinical effectiveness (as per the intended use)

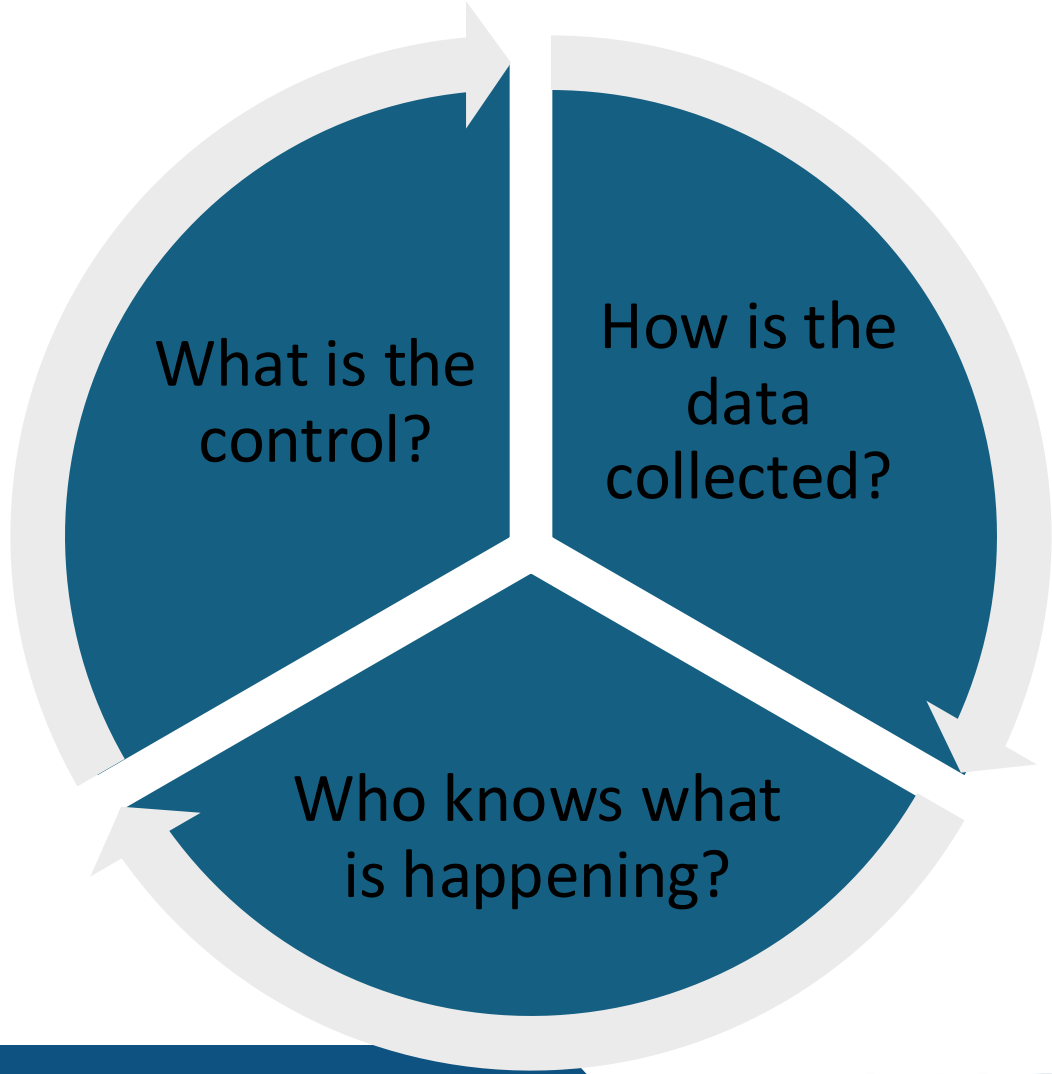
Respect rights of all stakeholders in order of criticality, mainly the safety, health and well being of involved human subjects


Prototype
Ownership of data
Patient population
Significant data
Robust statistics
Conditions of use

STUDY DESIGN: to be assessed

The best design that is technically possible





ENDPOINT: pilot studies

01	Essential Requirements	• not fully covered by technical tests/ device validation • clinical risks
02	Intended use(s) and performances	• Explorative • Dataset creation
03	Safety	• Side effects • Activation of alarms/protection • Ergonomic features
04	Information	• User education, skills and experience • Digital autonomy

ENDPOINT: pivotal study

01	Essential Requirements	• not fully covered by technical tests/ device validation • clinical risks
02	Intended use(s) and performances	• Expected clinical outputs • Expected benefits
03	Safety	• Side effects • Activation of alarms/protection • Ergonomic features
04	Information	• Evaluation of IFU, label • Onboarding and training • Digital autonomy

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Grazie per l’attenzione!

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