

Evidence & Precision Medicine

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Evidence: The available body of facts or information indicating whether a belief or proposition is true or valid.

www.lexico.com/definition/evidence

CERTAINTY LEVELS

Uncertain

Possible

Likely

**Definitely
true**

DATA LAKES

Demographic

Clinical

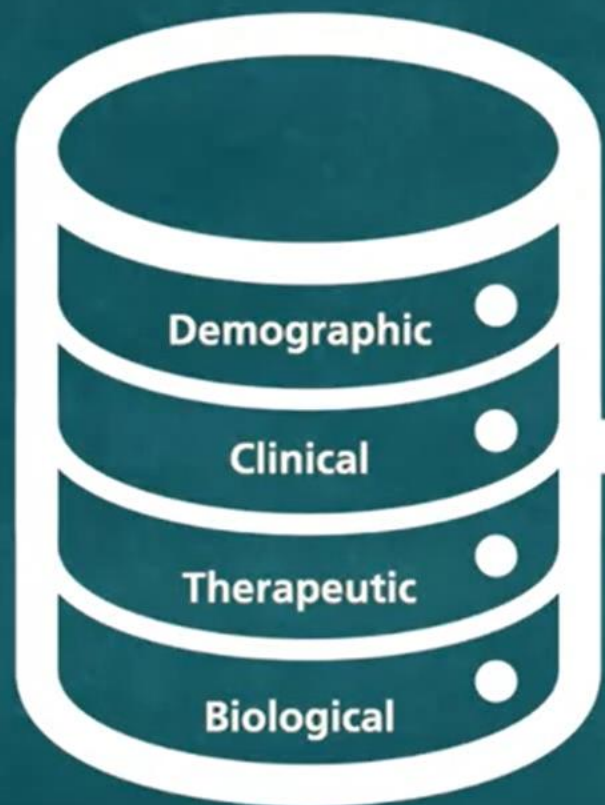
Therapeutic

Biological

Continued evidence building is needed

Documentation should be:

- Comprehensive
- Updated
- Reader-friendly
- Transparent



TWO SYSTEMS TO ENSURE ETHICAL AND LEGAL DATA PROCESSING

Ethics committee

Research ethics

- Human rights
- National Legislation
- Ethical Guidelines

Research institution

Data protection

- GDPR
- National data protection legislation

CONSENT

Research ethics instrument

Informed consent
to research
participation

Data protection instrument

Lawful basis for
data processing
(which can,
but does not
need to be,
consent)

ETHICS APPROVAL

Research ethics instrument



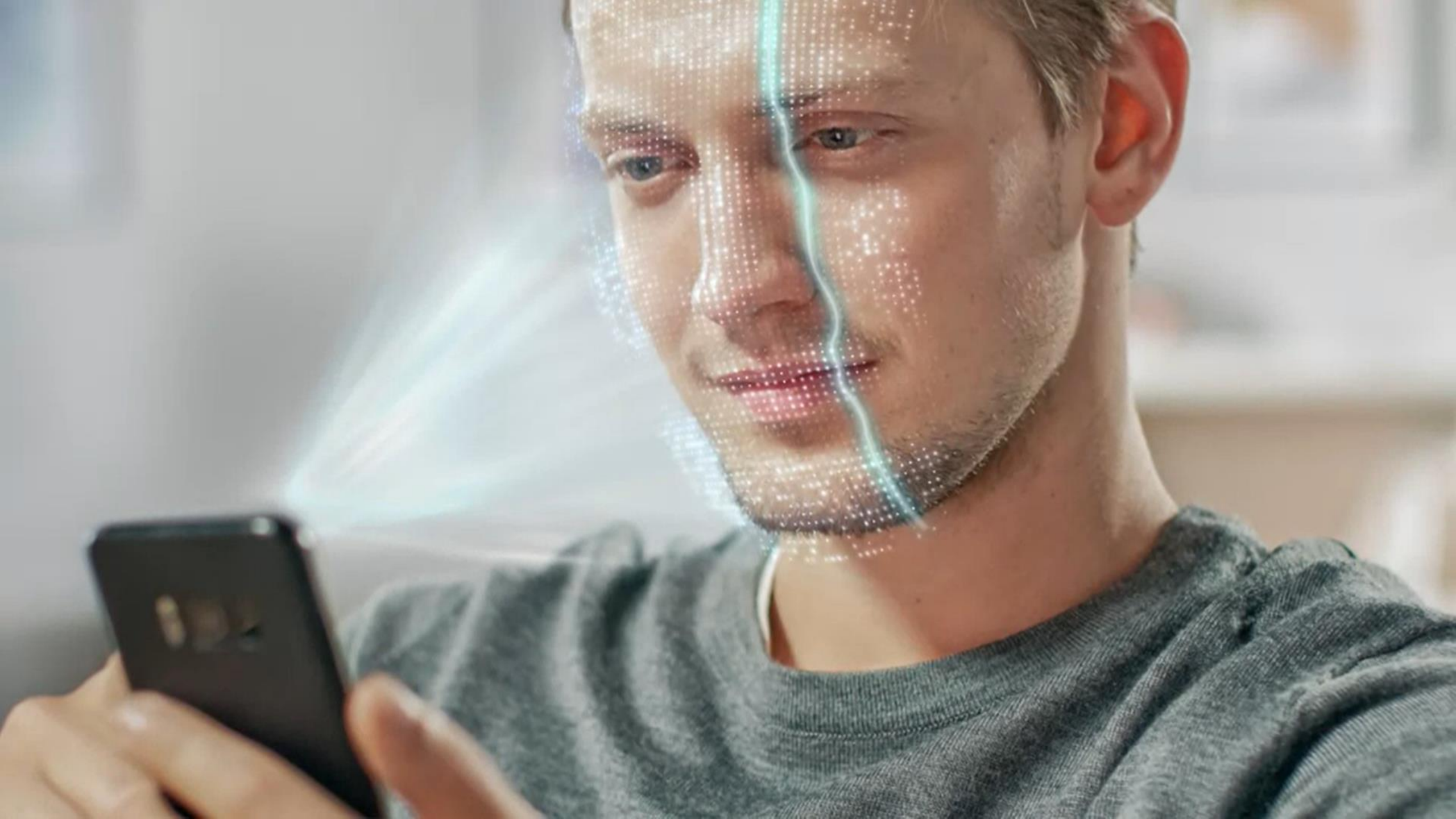
INFORMATION SECURITY

Appropriate to the risks to the research participants

**Unauthorized
access or
disclosure**

**Accidental
deletion**

**Destruction
of data**



TRANSPARENCY

Challenging to explain AI tools in a manner that is:

**Easily
understandable**

Sufficient

Correct

FAIRNESS

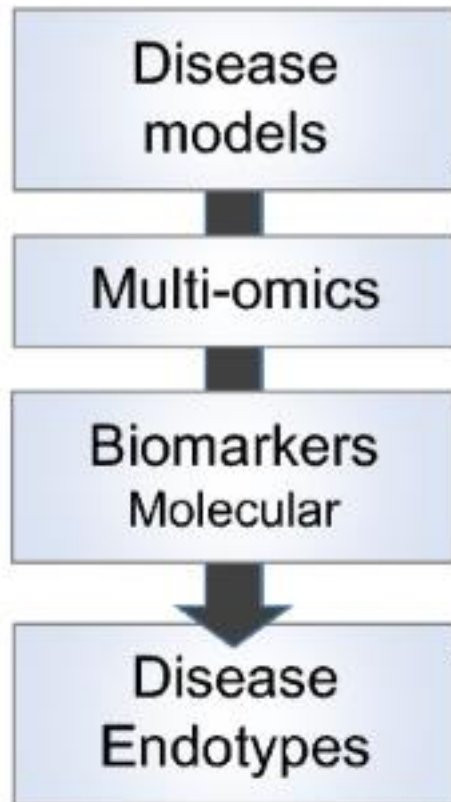
**Biased
training data**



**Biased
algorithm**

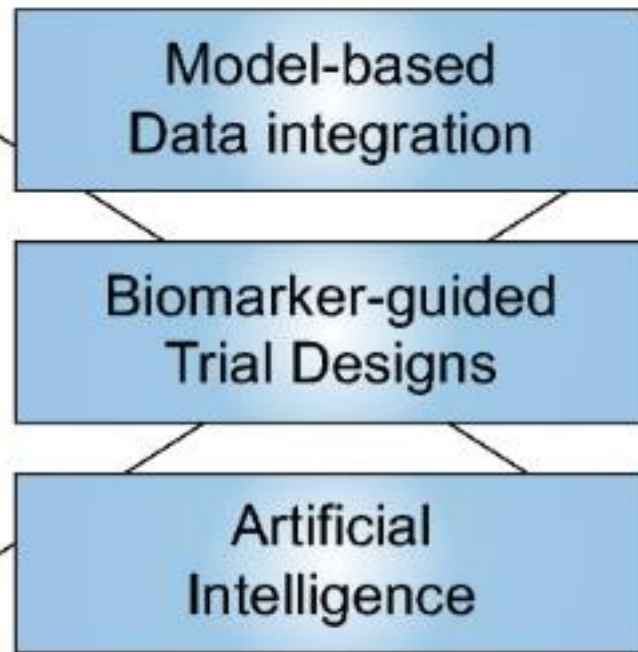
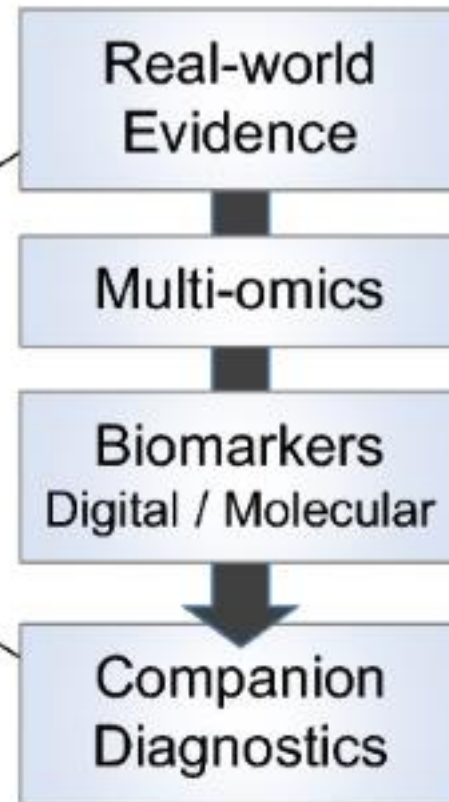
Translational Medicine

Early Development



Precision Medicine

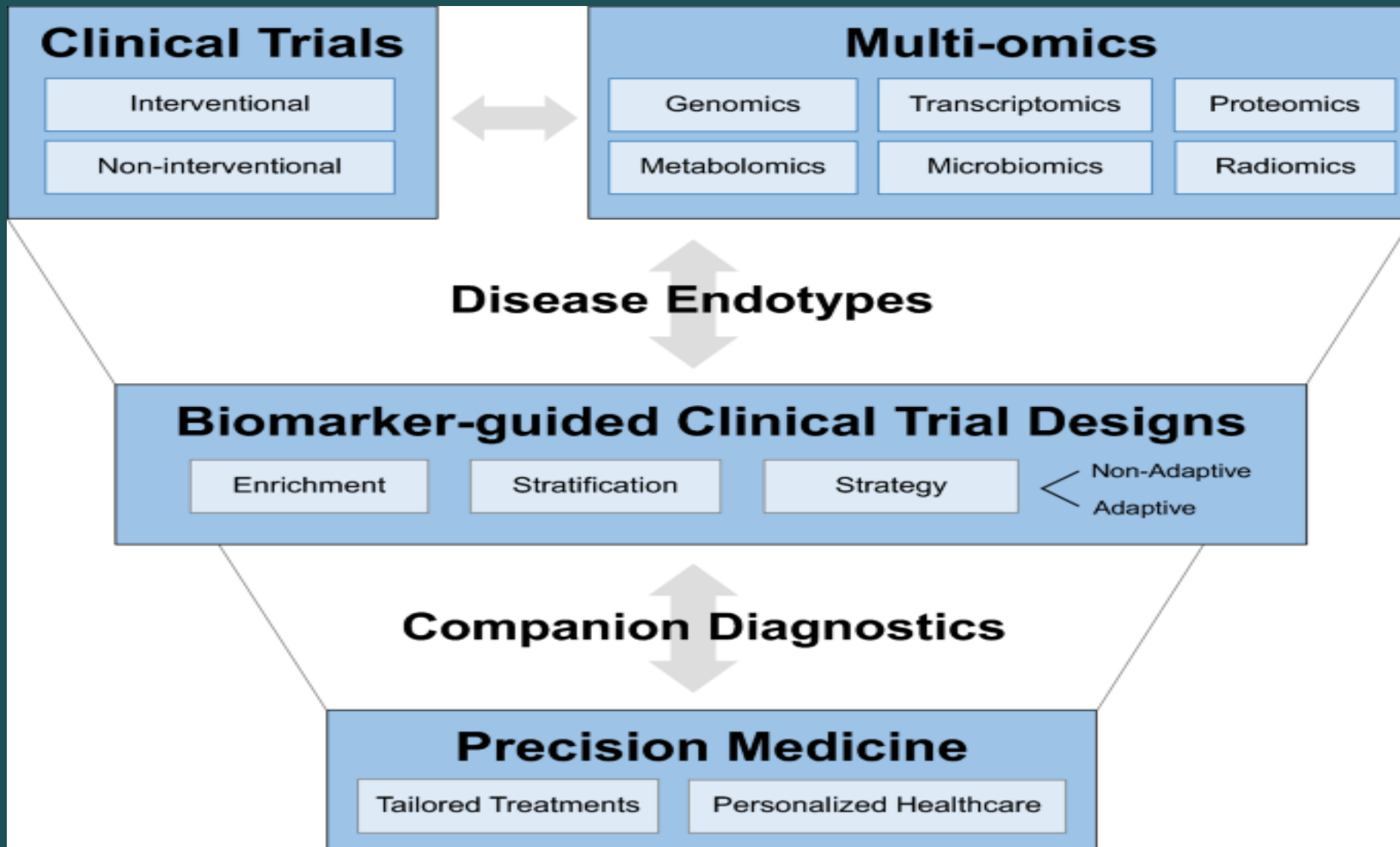
Late Development



Translational Precision Medicine



Hartl, D., de Luca, V., Kostikova, A. *et al.* Translational precision medicine: an industry perspective. *J Transl Med* **19**, 245 (2021). <https://doi.org/10.1186/s12967-021-02910-6>



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Precision Medicine - Paradigm Shift



*Application of rules, algorithms and reference databases enables **ACTIONABLE** clinical decision support & **PRECISE/EFFICIENT** care*

