JA PCM
Joint Action Personalised Cancer Medicine

JA PCM Evaluation Glossary

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Adoption

The implementation of an innovative intervention across different settings (contexts) and intervention agents (implementers) because it addresses relevant problems and produces outcomes perceived as valuable. Adoption can be measured by the number, proportion, and representativeness of settings and implementers undertaking the intervention, and is influenced by factors such as resources, expertise, and context[1].

Adopter

An individual, organization, healthcare provider, healthcare system, or other entity that implements and uses an innovation in practice[2,3]. Early Adopters are organizations, healthcare providers, or healthcare systems that implement an innovation in real-world conditions at an early stage to generate evidence regarding feasibility, value, and implementation requirements. Future Adopters are organisations, healthcare providers, or healthcare systems that review the outcomes of a Proof of Concept[4] or the implementation of innovative interventions to determine how well the generated evidence supports their identified needs, priorities, and decision-making processes. Late majority are organisations, healthcare providers, or healthcare systems that adopt an innovation after the average participant, once enough evidence has been generated. Laggards usually have lower financial liquidity and tend to adopt innovations when are considered "traditions", routine practice.

Benchmarking Analysis

An analytical comparison of available technologies, services, procedures, solutions or interventions against existing standards, current practices or alternatives to evaluate their ability to address identified needs and support adoption decisions[5].

Business Case

It is a document that provides contextual information to decision makers about the costs and benefits of an intervention, the strategic alignment and/or the business problems that the intervention aims to solve[6,7].

Business Model

The rationale describing how an organization creates, delivers, and captures value through an innovation, including its resources, activities, partnerships, beneficiaries, and financial sustainability mechanisms[8].

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[1] World Health Organization. A guide to implementation research in the prevention and control of noncommunicable diseases. World Heal. Organ. (2016).

[2] Rogers, Everett M. *(1983). Diffusion of innovations (3rd ed.). New York: Free Press of Glencoe.*

[3] MEYER, G. (2004). Diffusion Methodology: Time to Innovate? *Journal of Health Communication*, *9*(sup1), 59–69. https://doi.org/10.1080/10810730490271539

[4] Prats Balado, C., Castellano, J. M., Solís Díez, G., Mias, R., Molina-Barceló, A., Romeo Cervera, P., van Schaik, L., Retèl, V., Valls-Comamala, V., Maspons, R., & Alessandrello, R. (2025). D3.4 Evaluation Guide Report (Version V1.1). Zenodo. https://doi.org/10.5281/zenodo.15349266)

[5] Purwanto, Agus, Benefit of Benchmarking Methods in Several Industries: A Systematic Literature Review (2020). Sys Rev Pharm 2020;11(8):508-518, Available at SSRN: https://ssrn.com/abstract=3986775

[6] European Commission: Directorate-General for Digital Services, PM² Project management methodology –Guide3.1, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2799/970188

[7] Winn, B., & Stack, R. (2015). INSPIRE: D3.1 Economic Determinants of PCP. Zenodo. https://doi.org/10.5281/zenodo.15830020

[8] Alexander Osterwalder and Yves Pigneur defined the modern business model framework in their foundational 2010 book, *Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers*

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Capability

What you are able to do.
The ability, competence, or power to perform a task or achieve an outcome. Capability is the 'the ability of an **organization** to perform a coordinated set of tasks, utilizing organizational resources, for the purpose of achieving a particular end result'[9].

Capacity

How much you can do. The resources, volume, or extent to which something can be performed.

Organizational Capacity refers to the establishment of actions, routines, or processes within a company with the objective of achieving competitive advantages, being understood as those differentiating elements that allow a company to obtain a better position with respect to the competition because it has valuable resources, with the sense of exploits the opportunities and neutralizes the threats[10].

Organizational Capacity to Change refers to the overall openness and tolerance to change and to the extent organizational aspects support or hamper change in general[11].

Desirability

Determines the added value for stakeholders, including patients, citizens, researchers, healthcare professionals, healthcare providers, and health systems. It assesses whether the idea addresses a genuine need or merely a perceived want, how the value proposition should ultimately be deployed, and what support is required to ensure its successful delivery to the intended beneficiaries[12].

Evidence

The best evidence is the evidence that provides the most valid and objective answer to the different questions arising in clinical practice and healthcare resource management, drawing on the synthesis and integration of scientific findings from health sciences as well as social, economic, and political sciences[13].

Evidence Generation

In case of health products, the evidence generation is the systematic process of collecting and analysing data through research and evaluation to produce reliable knowledge that informs health-related decisions[14].
For non-product interventions, organisational changes, service transformations, or policy initiatives, the level[15] and type of evidence generated should be proportionate to the decision context and aligned with the best available methods for answering the specific questions arising in clinical practice, healthcare delivery, and health system resource management.

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[9] Helfat, C.E., & Peteraf, M.A. (2003). The Dynamic Resource-Based View: Capability Lifecycles. Strategic Management Journal, 24(10), 997-1010.)

[10] Escamilla-Solano, S., Plaza-Casado, P., Prado-Román, M. (2020). Organizational Capability. In: Carayannis, E.G. (eds) Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship. Springer, Cham. https://doi.org/10.1007/978-3-319-15347-6_200016

[11] Mladenova, I. (2022). Relation between Organizational Capacity for Change and Readiness for Change. Administrative Sciences, 12(4), 135. https://doi.org/10.3390/admsci12040135

[12] https://ecolecanada.gc.ca/tools/jobaids/pdfs/mission-canvas-eng.pdf

[13] Granados A. HEALTH TECHNOLOGY ASSESSMENT AND CLINICAL DECISION MAKING:: Which Is the Best Evidence? *International Journal of Technology Assessment in Health Care*. 1999;15(3):585-592. https://doi.org/10.1017/S0266462399153121

[14] World Health Organization. (n.d.). *Evidence generation*. World Health Organization. https://www.who.int/our-work/science-division/research-for-health/optimizing-research-processes/evidence-generation

[15] Vatkar A, Kale S, Shyam A, Srivastava S. Understanding the Levels of Evidence in Medical Research. J Orthop Case Rep. 2025 May;15(5):6-9. doi: 10.13107/jocr.2025.v15.i05.5534. PMID: 40351623; PMCID: PMC12064251.

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Exploitation

Exploitation makes concrete use of results for commercial, societal and political purposes. It consists in the process of using and further developing research results to generate scientific, societal, policy, economic, or healthcare impact beyond the duration of the research[16].

Feasibility

The degree to which a new treatment or innovation can be effectively adopted and implemented within a particular organizational or operational setting[17].
Capabilities[18,19] in terms of key resources (physical, intellectual, human) and partners (what resources can bring and what activities can develop) to develop the activities to generate and measure the expected impact (likelihood of cost-effectiveness, etc), outcomes (adherence, etc) and outputs (acceptability, etc) by getting "buy in" from all the impacted stakeholders and with given available budget[20].

Freedom to Operate

Freedom to operate means you are free to use your product or service as you have planned, without incurring legal liability for this use. Legal liability can arise from the unauthorized use of protected intellectual property (IP) owned by a third party. Whenever a company is planning to develop and launch a new product, a major risk, particularly in technology sectors where there is extensive patenting, is that commercialization may be blocked by a competitor who holds a patent for a technology incorporated within that product. This is why many companies, at an early stage, seek to secure their "freedom to operate," i.e. to ensure that the commercial production, marketing and use of their new product, process or service does not infringe the IP rights of others[21].

Governance Model

The structure of roles, responsibilities, decision-making mechanisms, and accountability arrangements through which an organization, project, or partnership is directed and controlled[22].

Health Equity

Absence of unfair, avoidable, or remediable differences in health status among population groups defined as socially, economically, demographically or geographically. Implies that each person should attain their full health potential and that no one should be disadvantaged from achieving this because of their social position or other socially determined circumstances. This refers to every citizen and not just to a particularly disadvantaged population segment[23].

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[16] European Commission: European Research Executive Agency, *Communication, dissemination & exploitation what is the difference and why they all matter*, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2848/289075

[17] Ogundahunsi, O., & Kamau, E. M. (Eds.). (2018). *Implementation research toolkit* (2nd ed.). World Health Organization. Licence: CC BY-NC-SA 3.0 IGO https://iris.who.int/bitstream/handle/10665/363749/9789241513685-eng.pdf

[18] Skivington K. et al. (2021). A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021;374:n2061 | doi: 10.1136/bmj.n2061

[19]Osterwalder, A., Pigneur, Y., Bernarda, G., & Smith, A. (2014). Value Proposition Design. Wiley.

[20]Strategyzer. (2022). The Mission Model Canvas: An adapted business model canvas for mission-driven organizations. Strategyzer. https://www.strategyzer.com/library/the-mission-model-canvas

[21] World Intellectual Property Organization. (n.d.). *Tool 5: Freedom to operate*. In *TISC Technology Innovation Support Center Toolkit*. https://www.wipo.int/documents/d/tisc/docs-en-tisc-toolkit-freedom-to-operate-description.pdf

[22] OECD (2023), *G20/OECD Principles of Corporate Governance 2023*, OECD Publishing, Paris, G20/OECD Principles of Corporate Governance 2023.

[23] World Health Organization (WHO). Health promotion glossary of terms 2021. Geneva; 2021. Available from: https://www.who.int/publications/i/item/9789240038349

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More specifically, **equity in genomics** refers to the global applicability of genomic knowledge, fair and equitable access to genomic services such as testing and counselling, and unbiased implementation of genomic medicine. Equity in genomics is based on an improved understanding of the interaction among biological, social and environmental factors in disease occurrence[24].

Health Intervention

An act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions[25,26]. Health intervention is described in term of three axes:

- Target - entity on which the Action is carried out
- Action - deed done by an actor to the Target
- Means - processes and methods by which the Action is carried out

Health Intervention/Change/Transformation Readiness

The degree to which an innovation, innovator, adopter, and any other stakeholder impacted by the transformation (organization, healthcare system, etc.) possesses the capabilities, resources, evidence, and motivation required to undertake a specific action or move to the next stage of implementation or change[27,28].

Health Intervention Maturity Level

The stage of development and adoption of an innovation/intervention/change/transformation as determined by predefined criteria related to equity, impact assessment, desirability, feasibility, viability and reimbursement approach[29].

Maturity level	**Definition**
Level 1	From design to proof of concept; evidence generation and implementation planning underway.
Level 2	From early adoption in real-world settings to adoption across multiple healthcare providers or within one healthcare system; evidence and implementation pathways being validated.
Level 3	From adoption within one healthcare system to scale-up across multiple healthcare systems, supported by evidence, equity outcomes, and reimbursement strategies.

[24] Jooma S, Hahn MJ, Hindorff LA, Bonham VL. Defining and Achieving Health Equity in Genomic Medicine. Ethn Dis. 21 de febrero de 2019;29(Suppl 1):173-8.

[25] OECD (2022), Guidebook on Best Practices in Public Health, OECD Publishing, Paris, https://doi.org/10.1787/4f4913dd-en

[26] World Health Organization. (2023). *Compendium of WHO and other UN guidance on health and environment: Version with International Classification of Health Interventions (ICHI) codes*. World Health Organization. https://iris.who.int/

[27] Domlyn, A. M., Scott, V., Livet, M., Lamont, A., Watson, A., Kenworthy, T., Talford, M., Yannayon, M., & Wandersman, A. (2021). R=MC2 Readiness Building Process: A Practical Approach to Support Implementation in Local, State, and National Settings. Journal of Community Psychology,1–21. https://doi.org/10.1002/jcop.22531

[28] Weiner, B.J. A theory of organizational readiness for change. *Implementation Sci* **4**, 67 (2009). https://doi.org/10.1186/1748-5908-4-67

[29] Solís Díez, G., Prats Balado, C., Valls-Comamala, V., CASTELLANO-GARCIA, J. M., MIAS, R., Molina-Barceló, A., Romeo Cervera, P., Pinto-Carbó, M., Retèl, V., van Schaik, L., Van den Bulcke, M., Van Valckenborgh, E., Maspons, R., & Alessandrello, R. (2026). A value-based evaluation framework for guiding the adoption and scale-up of cancer genomics interventions. https://doi.org/10.1159/000551155

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Health Technology Assessment (HTA)

Health Technology Assessment (HTA) summarises information about medical, economic, social and ethical issues related to the use of a health technology. Examples of health technologies include medicinal products, medical equipment for diagnostic and treatment, prevention methods[30].

Specifically, **early HTA** is a health technology assessment (HTA) conducted to inform decisions about subsequent development, research, and/or investment by explicitly evaluating the potential value of a conceptual or actual health technology[31].

Health Transformation

A structured and sustainable process of change through which healthcare actors (providers, systems, etc.) modify practices, pathways, structures, capabilities, and relationships to improve value, outcomes, equity, sustainability and resilience (adapted from[32]). A method that can be used to plan and depict the transformation is the Theory of Change.

Horizon Scanning

The systematic examination of potential threats, opportunities, developments, and emerging innovations that may affect future health systems or policy decisions[33].

Impact

Refers to the effects or consequences of a health technology on patients, health outcomes, healthcare systems, resources, and society compared with existing practice. This is operationalized through assessment of clinical, economic, organisational, social, ethical and legal domains[34]

Specifically, **impacted stakeholders** are those individuals or groups affected by the outcomes, implementation, adoption, scale-up or consequences of an intervention, change, transformation across the healthcare continuum, regardless of their direct involvement.

Implementation

The implementation of innovation means an innovation has ceased to be innovative. It means that a method, technology, or approach to a problem has moved from the experimental edges of an organization to the core of its work: no longer a novelty, but something normal and institutionalized[35]. Implementation is comprehensive of a specified set of activities designed to put into practice and real-world settings a policy or innovative intervention of known dimensions.[36]

Innovation

A new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)[37].

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[30] European Commission. (n.d.). *Overview: Health Technology Assessment (HTA)*. https://health.ec.europa.eu/health-technology-assessment/overview_en

[31] Grutters JPC, Bouttell J, Abrishami P, et al. Defining early health technology assessment: building consensus using Delphi technique. *International Journal of Technology Assessment in Health Care*. 2025;41(1):e34. doi:10.1017/S0266462325100123

[32] World Health Organization. *A global health strategy for 2025-2028: advancing equity and resilience in a turbulent world: Fourteenth General Programme of Work (GPW 14).* Geneva: WHO; 2024.

[33] Emerging trends and technologies: a horizon scan for global public health. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO

[34] https://www.who.int/health-topics/health-technology-assessment#tab=tab_1

[35] Kumpf, B. and E. Proud (2022). "The Adoption of Innovation." Stanford Social Innovation 754 Review, August 2022.

[36] World Health Organization. A guide to implementation research in the prevention and control of noncommunicable diseases. World Heal. Organ. (2016).

[37] OECD, & Eurostat. (2018). *Oslo manual 2018: Guidelines for collecting, reporting and using data on innovation* (4th ed.). OECD Publishing. https://doi.org/10.1787/9789264304604-en

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Innovator

The individual, team, or organisation that develops and introduces an innovation for use by potential users or adopting organisations[38].

Need

Needs are associated with everything human beings require to function well. As such they are different from wants, which are things people would like to have[39].

Health Need is the capacity to benefit from health care. Health care means treatment, prevention and supportive care that is effective – either alone or as part of a care pathway – in improving, maintaining, or slowing the deterioration of health now or in the future (or both). Need is for 'appropriate' health care: this excludes care that is known to be cost-ineffective and includes cost-effective care. For care of unknown cost-effectiveness, need is for the right care provided in the right place and at the right time[40]. Needs can be normative, expressed, comparative or felt. Health-related needs can be met by targeted healthcare interventions, health system-wide interventions, social services, or wider policies that have an impact on health[41].

Societal or community needs are the gap or discrepancy between the current conditions - 'what is' - and the ideal conditions - 'what should be', any identification of need contains an 'implicit notion of what constitutes an acceptable minimum standard of personal or community wellbeing'[42].

Health and societal unmet need are a shortfall of appropriate services and could complement conventional methods of determining inequity in the utilisation of health care. Health unmet needs can be unperceived, chosen, unchosen, clinician validated, subjective unmet expectations[43].

Heath technology unmet need is a need that is not adequately addressed through the existing either health technologies or solutions on the market. This gap may create demand for innovative products, services, or approaches capable of delivering better outcomes than currently available alternatives[44]. (In this definition we understand health technology including medicines, medical devices, assistive technologies, techniques and procedures developed to solve health problems and improve the quality of life[45].)

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[38] European Commission. (2026, September 9). *Proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening the Union innovation ecosystem and amending Regulation (EU) 2017/1001 (European Innovation Act) (COM(2026) 567 final; 2026/0264 (COD)).* Publications Office of the European Union. https://research-and-innovation.ec.europa.eu/document/download/961e80de-b6a0-4c34-9b2f-b66ea0bb7ee1…

[39] Wouter Boon, Jakob Edler, Demand, challenges, and innovation. Making sense of new trends in innovation policy, *Science and Public Policy*, Volume 45, Issue 4, August 2018, Pages 435–447, https://doi.org/10.1093/scipol/scy014

[40] Rodriguez Santana I, Mason A, Gutacker N, Kasteridis P, Santos R, Rice N. Need, demand, supply in health care: working definitions, and their implications for defining access. *Health Economics, Policy and Law*. 2023;18(1):1-13. doi:10.1017/S1744133121000293

[41] Maertens de Noordhout, C., Levy, M., Claerman, R., De Jaeger, M., De Pauw, R., Kohn, L., Schönborn, C., & Cleemput, I. (2025). *Identification of health-related needs: The needs examination, evaluation and dissemination (NEED) assessment framework*. **Health Policy, 155**, 105263. https://doi.org/10.1016/j.healthpol.2025.105263

[42] Australian Institute of Family Studies. (n.d.). *Needs assessment*. Australian Institute of Family Studies. https://aifs.gov.au/resources/practice-guides/needs-assessment

[43] Rodriguez Santana I, Mason A, Gutacker N, Kasteridis P, Santos R, Rice N. Need, demand, supply in health care: working definitions, and their implications for defining access. *Health Economics, Policy and Law*. 2023;18(1):1-13. doi:10.1017/S1744133121000293

[44] European Commission. (2021). *Commission Notice: Guidance on Innovation Procurement (2021/C 267/01)*. Official Journal of the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021XC0706(03)

[45] World Health Organization Regional Office for Europe. (2023, November 24). *Health technologies*. World Health Organization. https://www.who.int/europe/news-room/fact-sheets/item/health-technologies

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Payor (Payer) / Insurer

A payor in healthcare is any entity that pays for medical services on behalf of patients. While providers (doctors, hospitals, clinics) deliver care, payors are the organizations that finance it by processing claims and reimbursing providers after services are rendered[46].
Single payer refers to a health system that is financed by a single entity; in its common usage, that single entity is government. Government is the payer for services, and such payments are financed by taxes, but there is no implication that government employs the providers or actually owns or operates the health system[47].
Multiple payer refers to a health system that is financed through more than a single entity, one of which may include government. Private health insurance companies participate in multiple-payer systems, with financing through individual premiums paid directly by beneficiaries, employers, and, in some cases, government[48].

Proof of Concept (PoC)

POCs (Proof of Concept) refer to specific testing methodologies aimed at the parameter being evaluated. It is a generic terminology used in several areas when it is intended to verify a requirement contained in a device prototype[49].
In case of medicine, A proof of concept (POC) trial is one type of trial carried out early in the clinical development phase of a medicine (in humans). Phase II trials usually begin with a proof of concept trial, which aims to show that the medicine interacts with its intended target and affects the disease in question[50].

Public Procurement

Public procurement contracts cover supplies, services and works purchased by the public sector. Contracts over a certain value are subject to European Union (EU) rules and procedures. These rules seek to ensure fair treatment for businesses and openness in the handling of calls to tender. They should be seen in the context of greater competition and the freedom to provide services within the EU single market[51].

Public Procurement of Innovation

Procurement of innovation is the public procurement instrument to be used when unmet needs or new expectations relative to health technologies are not adequately addressed through the existing solutions and services on the market (adapted from [52,53]).

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[46] ScienceInsights. (2026, March 11). *What is a payor in healthcare? Definition and types*. ScienceInsights. https://scienceinsights.org/what-is-a-payor-in-healthcare-definition-and-types/

[47] Donnelly PD, Erwin PC, Fox DM, Grogan C. Single-Payer, Multiple-Payer, and State-Based Financing of Health Care: Introduction to the Special Section. Am J Public Health. 2019 Nov;109(11):1482-1483. doi: 10.2105/AJPH.2019.305353. PMID: 31577483; PMCID: PMC6775924.

[48] Donnelly PD, Erwin PC, Fox DM, Grogan C. Single-Payer, Multiple-Payer, and State-Based Financing of Health Care: Introduction to the Special Section. Am J Public Health. 2019 Nov;109(11):1482-1483. doi: 10.2105/AJPH.2019.305353. PMID: 31577483; PMCID: PMC6775924.

[49] Ayello, M., & Lopes, Y. (2023). *Interoperability based on IEC 61850 standard: Systematic literature review, certification method proposal, and case study*. Electric Power Systems Research, 220, 109355. https://doi.org/10.1016/j.epsr.2023.109355

[50] European Patients' Academy (EUPATI). (n.d.). *Proof of concept (POC)*. EUPATI Toolbox. https://toolbox.eupati.eu/glossary/proof-of-concept/

[51] European Union. (n.d.). *Public procurement*. EUR-Lex. Retrieved October 1, 2026, from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:public_procurement

[52] European Commission. (n.d.). Public procurement of innovation. https://single-market-economy.ec.europa.eu/single-market/public-procurement/strategic-procurement/public-procurement-innovation_en

[53] Monteiro, B., A. Hlacs and P. Boéchat (2024), "Public procurement for public sector innovation: Facilitating innovators' access to innovation procurement", OECD Working Papers on Public Governance, No. 80, OECD Publishing, Paris, https://doi.org/10.1787/9aad76b7-en.

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- **Pre-Commercial Procurement** (PCP): buying the process of innovation – research and development services – with (partial outcomes - the public buyer buys the research and development services of products, services or processes, which do not exist yet. The public buyer describes its need, prompting businesses and researchers to develop innovative products, services or processes to meet the need.
- **Public Procurement of Innovation** (PPI): buying the outcomes of innovation created of others - the public buyer, instead of buying off-the-shelf, acts as an early adopter and buys a product, service or process that is new to the market and contains substantially novel characteristics.

Reimbursement

Covering the cost of health care services, including medicines, by a third-party payer (e.g. a public payer such as a social health insurance fund or national health service)[54].

Research

Research and Development (R&D) is the Creative and systematic work undertaken to increase the stock of knowledge, including knowledge of humankind, culture and society, and to devise new applications of available knowledge[55]. The activity must be: novel, creative, uncertain, systematic, transferable and/or reproducible. The term R&D covers three types of activity: basic research, applied research and experimental development. **R&D personnel** include all persons engaged directly in R&D.
Health research supports health systems in the delivery of better, fairer and more equitable health care to people. It does so by identifying challenges and providing best solutions, monitoring how health systems perform and producing new knowledge for better technologies and improved approaches to public health. Health research must serve as a driver for health policy and practice. For this to happen, the health research systems not only have to be fully accountable for the sake of transparency, but also have to be capable of delivering the desired returns, to justify the allocation of scarce resources to research and development[56]. **Health researcher** is a professional involved in generating, evaluating, interpreting, or translating knowledge and evidence to support innovation development, inform decision-making, and reduce uncertainties regarding clinical, economic, and implementation outcomes, with varying proximity to patient care depending on the research stage and decision-making.

Risk

The probability of adverse or beneficial events, following a known probability distribution. The International Organization for Standardization (ISO) defines risk as the effect of uncertainty on objectives[57]. Risks can be characterized by their identification, probability to happen and impact they generate.

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[54] Vogler, S., Paris, V., & Panteli, D. (2018). *Ensuring access to medicines: How to redesign pricing, reimbursement and procurement?* (Policy Brief No. 30). World Health Organization, Regional Office for Europe. https://eurohealthobservatory.who.int/publications/i/ensuring-access-to-medicines-how-to-redesign-p...

[55] Organisation for Economic Co-operation and Development (OECD). (2015). *Frascati manual 2015: Guidelines for collecting and reporting data on research and experimental development*. OECD Publishing. https://doi.org/10.1787/9789264239012-en

[56] Fathalla, M. F., & Fathalla, M. M. F. (2004). *A practical guide for health researchers*. World Health Organization Regional Office for the Eastern Mediterranean. https://iris.who.int/server/api/core/bitstreams/01e89af6-a30d-466b-8804-3cedba3a19cf/content

[57] Organisation for Economic Co-operation and Development (OECD). (2023). *Managing risks in the public procurement of goods, services and infrastructure*. OECD Publishing. https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/06/managing-risks-in-the-public-procurement-of-goods-services-and-infrastructure_b0d29f96/45667d2f-en.pdf

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Risk Management is the continuous and systematic process for identifying, assessing, and managing risks. The management of project risks provides increased visibility and confidence in dealing with uncertainty and proactively supports the achievement of the project objectives. The Risk Management Process can be documented in the Risk Management Plan. A Risk Log is used to document and communicate the risks, the relevant risk response actions and responsibilities[58].

Scale-up

The process of expanding, adapting, and sustaining successful projects, programmes, policies, services, products, or delivery models over time to achieve greater impact[59]. Scale-up can occur through:

- Vertical scale-up (institutionalization): embedding the intervention within policies, systems, or organizational structures.
- Horizontal scale-up (expansion and replication): extending the intervention to new settings, populations, or organisations.[60]

Social Determinants of Health

The social, cultural, political, economic and environmental conditions in which people are born, grow up, live, work and age, and their access to power, decision-making, money and resources that give rise to these conditions of daily life[61].

Stakeholder

Any individual, group, or organisation that is involved in or affected by the development, implementation, or use of digital solutions and services. This can include public sector organisations, private sector entities, civil society groups, and individual citizens. Stakeholders may have varying levels of interest in joining up initiatives and may be involved in different capacities such as users, developers, policymakers etc[62].

State-of-the-Art Analysis

An assessment of current knowledge, technologies, services, and practices available in a field to determine the degree of novelty of a proposed innovation in comparison with existing solutions and prevailing market or industry standards[63].

Theory of Change

A method that explains how a given intervention, or set of interventions, is expected to lead to specific development change, drawing on a causal analysis based on available evidence. A theory of change must be driven by sound analyses, consultation with key stakeholders and learning on what works and what does not in diverse contexts drawn from the experience. A theory of change helps to identify solutions to effectively address the causes of problems that hinder progress and guide decisions on which approach should be taken, considering comparative advantages, effectiveness, feasibility and uncertainties that are part of any

[58] European Commission. (2015). *PM² Project Management Methodology Guide*, version 2.5, section 8, "Monitor & Control

[59] Hartmann, Arntraud, and Johannes F. Linn. 2008. *Scaling Up: A Framework and Lessons for Development Effectiveness from Literature and Practice*. Wolfensohn Center for Development Working Paper No. 5. Washington, DC: The Brookings Institution. https://doi.org/10.2139/ssrn.1301625

[60] World Health Organization. A guide to implementation research in the prevention and control of noncommunicable diseases. World Heal. Organ. (2016).

[61] World Health Organization. A conceptual framework for action on the social determinants of health. Social Determinants of Health discussion paper 2. Geneva: World Health Organization, 2010

[62] European Commission. (n.d.). *Stakeholder*. Interoperable Europe Portal, Glossary

[63] OECD/Eurostat (2018), *Oslo Manual 2018: Guidelines for Collecting, Reporting and Using Data on Innovation, 4th Edition*, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris/Eurostat, Luxembourg, https://doi.org/10.1787/9789264304604-en.

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change process. A theory of change also helps to identify the underlying assumptions and risks that will be vital to understand and revisit throughout the process to ensure the approach will contribute to the desired change[64].

Uncertainty

Uncertainty is intrinsic to the practice of clinical medicine and relates to all components of clinical care including diagnosis, management, outcomes, relationship-building, and affective experiences. Technical uncertainty arises from inadequate or incomplete scientific data and could be understood as data-related uncertainty. Personal uncertainty arises from an uncertain doctor-patient relationship. Conceptual uncertainty arises from a difficulty in applying data to real situations. Technical uncertainty could be considered first-order uncertainty and personal and conceptual uncertainty as second-order, or metauncertainty. First-order uncertainty is derived from uncertain probability of future outcomes and relates to scientific nature itself, whereas second-order uncertainty occurs when applying data to patient care, and it includes not only uncertainty that arises from real outcomes of given probabilities but also patients' desire or degree of interest regarding the outcome[65].

Use Case

A use case describes the interactions between a system and its user(s) (actors) to achieve a specific goal. It specifies the sequence of actions and responses between the actor and the system under particular conditions. The system can be equipment, devices, or processes[66].

Value Proposition

A clear statement describing the value and benefits that a product, service or innovation delivers to specific stakeholders or users compared with current practice, including how it addresses heath technology unmet needs, solves relevant problems, or improves outcomes (adapted from[67]).

Viability

Cost-effective interventions are not always affordable: usually the decision makers adopt programs in order of cost-effectiveness, continuing until the health budget is exhausted[68,69]. There is no standard definition of affordability, as it relates to the extent a patient or a service provider can pay for it. Something is affordable when one can manage it in terms of time, money or resources[70]. It is not necessarily just a question of price, but of its cost and payment model in the context of the timing, budget and resources of each health care system. On the other side opportunity cost[71] plays a crucial role in attempts to ensure that scarce resources are used efficiently. The opportunity cost is the benefits we stop perceiving as a result of not selecting the next best option when we have limited resources. Opportunity costs are not limited to monetary or financial costs: the actual cost of lost production, lost time, pleasure, or any other profit-making benefit should also be considered an opportunity cost.

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[64] Unicef partner Journey: https://unicefpartners.org/wp-content/uploads/2023/08/Theory-of-Change-guidance-and-checklist_Project-Oracle.pdf

[65] Kim K, Lee YM. Understanding uncertainty in medicine: concepts and implications in medical education. Korean J Med Educ. 2018 Sep;30(3):181-188. doi: 10.3946/kjme.2018.92. Epub 2018 Aug 27. PMID: 30180505; PMCID: PMC6127608. Understanding uncertainty in medicine: concepts and implications in medical education - PMC

[66] Project Management Institute. (2015). *Business analysis for practitioners: A practice guide*. Project Management Institute

[67] Osterwalder, A., & Pigneur, Y. (2010). *Business model generation: A handbook for visionaries, game changers, and challengers*. John Wiley & Sons.

[68] Evidence-based medicine (EBM) toolkit: A glossary of health economics terms, BMJ Best Practice

[69] Bilinski A, Neumann P, Cohen J, Thorat T, McDaniel K, Salomon JA (2017) When cost-effective interventions are unaffordable: Integrating cost-effectiveness and budget impact in priority setting for global health programs. PLoS Med 14 (10): e1002397

[70] EUnetHTA Adaptation glossary

[71] Olivera MJ. Opportunity cost and COVID-19: A perspective from health economics. Med J Islam Repub Iran. 2020 (29 Dec);34:177. https://doi.org/10.47176/mjiri.34.177

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Consequently, viability consists of assessing both the value and the financial sustainability of an innovative intervention.
On the one hand, it involves analysing:

- The value proposition of the innovative intervention for each affected stakeholder.
- The intervention's potential impact and the ability to generate and measure that impact.

On the other hand, it involves considering:

- The available budget and financial resources.

And it also includes designing an appropriate cost and financing structure to ensure the financial sustainability[72] of the innovative intervention, so that revenues, funding, or realised benefits cover costs and support the achievement of long-term objectives.

[72] Isawy, Mahmoud & Marwan, Youssef. (2024). Economic Sustainability: Meeting Needs without Compromising Future Generations. International Journal of Economics and Finance

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