ASCERTAIN

GLOSSARY

Working definitions for ASCERTAIN

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WORKING DEFINITIONS FOR ASCERTAIN

PROJECT OVERVIEW

Project Title	Affordability and Sustainability improvements through new pricing, Cost-Effectiveness and ReimbursemenT models to Appraise INnovative health technologies
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HISTORY OF CHANGES

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INTRODUCTION

This glossary provides working definitions for the Horizon Europe-funded project ASCERTAIN (Affordability and Sustainability improvements through new pricing, Cost- Effectiveness and ReimbursemenT models to Appraise INnovative health technologies), which addresses the need of patients, physicians, payers, regulators, and manufacturers to improve the affordability and accessibility to innovative health technologies (including pharmaceuticals) in Europe.

ASCERTAIN seeks to promote access to affordable technologies, the need to stimulate innovation and entrepreneurship, and the need to consider the environmental impact of innovations.

Guided by a conceptual framework integrating pricing, health technology assessment and reimbursement/ payment, ASCERTAIN will develop open-access, easy to use, policy-supporting tools including pricing models and value assessment models, it addresses the need of patients, physicians, payers, regulators, and manufacturers to improve the affordability and accessibility to innovative health technologies (including pharmaceuticals) in Europe.

The project glossary is a working document to provide definitions for terms commonly used in the project.

Terms in this glossary are listed alphabetically. Please note that definitions may be subject to change during the project.

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CONSORTIUM PARTNERS

Erasmus University Rotterdam

MPE Myeloma Patients Europe

COMENIUS UNIVERSITY BRATISLAVA

UiO University of Oslo

Gesundheit Österreich GmbH

eha

AIM Healthcare and social benefits for all

OptiMedis

CHINO.IO

WEBSITE & SOCIAL MEDIA

www.access2meds.eu

www.youtube.com/@ascertainproject

www.linkedin.com/company/ascertain-eu

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GLOSSARY

Term	Definition	Source
Academia	The part of society, especially universities, that is connected with studying and thinking, or the activity or job of studying. Within the context of ASCERTAIN, academia refers to the stakeholder group of researchers working in academic institutions and universities.	Cambridge University Press (2024) adapted by ASCERTAIN Consortium
Access (Accessibility)	A patient's (or the collective) ability to obtain medical care, including medicinal products and medical devices, and a measure of the proportion of a population that reaches appropriate health services. This term covers geographic access and financial access, as well as the health literacy required to seek healthcare when appropriate.	WHO CC PPRI (2024) adapted by ASCERTAIN Consortium
Access-based price	Price for a medicinal product or medical device estimated with the objective of improving patient access through considering and reconciling the interests of stakeholders (for payers/governments: ensuring affordability for and financial sustainability of a country's healthcare system; for the industry: allowing cost recuperation and an appropriate profit, as well as providing incentives for development of innovative health technologies, and making a product or device available on a market).	ASCERTAIN Consortium
Accountability (in healthcare organisations and systems)	A governing body (e.g., government, regional health authority, healthcare board, professional association) is in a position to mandate providers or organizations to meet certain goals or objectives. Because of the authority or legitimacy of these governing bodies, providers or organizations believe they must account for their achievements in relation to such goals or objectives.	Denis (2014)

Term	Definition	Source
Added therapeutic value	The incremental therapeutic value brought by a new medicinal product or intervention compared with the best available treatment options already on the market. The therapeutic value can be defined in terms of patient-relevant endpoints and relevant levels of effectiveness, efficacy and safety. Synonymous with "added clinical value", "added therapeutic benefit".	Van Wilder et al. (2015) adapted by ASCERTAIN Consortium
Affordability	The extent to which medicinal products, medical devices and other health technologies are available to the people who need them at a price they / their health system can pay.	WHO CC PPRI (2024) adapted by ASCERTAIN Consortium
Anonymization	The process of removing personally identifiable information from data. This is done so that individuals cannot be identified.	ASCERTAIN Consortium
Availability (of information)	Information is available whenever it's needed by a person or team who has the right to see it.	ASCERTAIN Consortium
Budget impact	A budget is an estimate of revenues and expenditures for a given period. Budget impact refers to the total costs that pharmaceutical or medical device reimbursement and use entail with respect to one part of the health care system, pharmaceutical care, or to the entire health care system, taking into account the possible reallocation of resources across budgets or sectors of the health care system.	WHO CC PPRI (2024) adapted by ASCERTAIN Consortium
Confidentiality	This property ensures that information is not made available or disclosed to unauthorised individuals, entities or processes.	ASCERTAIN Consortium
Conformité Européenne (CE) marking of conformity/CE marking (CE)	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the EU Regulation 2017/745 and EU Regulation 2017/746 and other applicable Union harmonisation legislation providing for its affixing. Note: The addition of a four-digit number indicates that a Notified Body was involved in the conformity assessment process.	European Parliament/Council of the European Union (2017a) European Parliament/Council of the European Union (2017b) Windisch (2022)

Term	Definition	Source
Cost	The (monetary) value of resources that have to be sacrificed in order to acquire something. The cost of an item could reflect its monetary price, but could also reflect the time that must be spent in order to obtain the item. In health economics, costs usually reflect the expenditure of the healthcare system on resources such as treatments, monitoring, staff time and other consumables. These costs are, however, better thought of as the opportunity cost associated with 'what other benefits could the use of those same resources have achieved?' Thus, the true 'cost' of the use of a resource may depend upon whether it was already being used to its full capacity. Costs are often categorised into different types, such as direct and indirect costs (reflecting whether the costs fall to the health and social care provider, or to other sectors) or fixed and variable costs (reflecting the initial payment for equipment and the additional cost per use of the consumables). Another important distinction is between average cost and marginal cost: the latter (more important for economic evaluation) being the additional cost of one further unit of resource, which frequently declines as more resource units are consumed. Incremental cost, denoting the difference in overall costs associated with the use of an intervention compared with the use of an alternative, is usually a key output of an economic evaluation.	YHEC (2025) adapted by ASCERTAIN Consortium
Cost-based pricing	Cost-plus pricing is the practice of setting the price of medicinal products considering a wide range of costs, including those associated with research and development, manufacturing, regulatory processes and compliance, overheads and operational expenses, and profit. In the ASCERTAIN project, the term "cost-based pricing" is preferred to "cost-plus pricing".	WHO (2021) adapted by ASCERTAIN Consortium

Term	Definition	Source
Cost-effectiveness	Value for money. A specific health care treatment is said to be "cost-effective" if it gives a greater health gain than could be achieved by using the same resources in other ways. If the decision maker is generally willing to pay around 20,000 EUR per QALY gained for a new treatment and a cost-effectiveness analysis showed that an intervention produced 0.5 additional QALYs and was associated with additional costs of no more than 10,000 EUR, then an intervention would be considered cost-effective, or "good value".	WHO CC PPRI (2024) and YHEC (2025) adapted by ASCERTAIN Consortium
Cost-effectiveness acceptability curve (CEAC)	Cost-effectiveness acceptability curve is a graphical illustration of the uncertainty in a cost-effectiveness analysis based on the PA (see below). Each curve represents the probability for that intervention to be considered cost-effective according to increasing CET (see definition below)	Briggs (2006) and Fenwick et al. (2006)
Cost-effectiveness acceptability frontier (CEAF)	Cost-effectiveness acceptability frontier is a graphical illustration of the uncertainty in a cost-effectiveness analysis based on the PA (see below). The curve represents the optimal strategy, i.e. based on the strategy providing the highest value (NMB) according to increasing CET (see definition below).	Briggs (2006) and Fenwick et al. (2006)
Cost-effectiveness threshold (CET)	A cost-effectiveness threshold (CET) is the maximum acceptable value that a decision-maker or society is willing to pay for an extra unit of health outcome. The comparison of an ICER against a CET tells if a new intervention is deemed more (ICER<CET) or less (ICER>threshold) efficient in creating health than the intervention in the current healthcare system.	Drummond et al. (2015) adapted by ASCERTAIN Consortium
Clinician	A health professional caring for patients.	NCI (2024)
Data Breach	A security incident is defined as the unauthorised copying, transmission, viewing, theft or use of sensitive, protected or confidential data.	ASCERTAIN Consortium

Term	Definition	Source
Demand-side cost-effectiveness threshold	Demand-side cost-effectiveness thresholds are thresholds which are determined based on an approach that suggests that individuals are best positioned to make decisions about maximizing their own health utility, emphasizing the importance of aligning budget allocation with societal preferences. In this context, CETs are determined by assessing willingness-to-pay through contingent valuation surveys or using the value of statistical life methods.	Danzon et al. (2018) Vallejo-Torres et al. (2016) adapted by ASCERTAIN Consortium
Discount rate	The interest rate used to determine the present value of future health gain and costs. In economic evaluations, such as cost-effectiveness analyses, the discount rate helps adjust for the fact that people tend to value immediate benefits or costs more highly than those occurring in the future.	ASCERTAIN Consortium
Drug	see "Medicinal product"	
Economic evaluation	Economic evaluation in healthcare is the analysis of the costs and effects of alternative interventions that may be given to a defined population in order to support decision-making about reimbursement or implementation of the preferred interventions. Both the immediate costs and health effects and their 'downstream' consequences (future events averted) are considered. The output/result of an economic evaluation is an incremental cost-effectiveness ratio, which may be compared with a threshold value (willingness to pay for a unit of health outcome).	YHEC (2025)

Term	Definition	Source
Effectiveness	Extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice. Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice. The effectiveness of an intervention can differ from its efficacy. While effectiveness refers to the ability of an intervention (drug, device, treatment, test, pathway etc.) to provide the desired outcome(s) in the relevant patient population, efficacy is the benefit of an intervention gained under ideal conditions, such as in a randomised controlled trial. "Ideal conditions" refers to an experimental and controlled setting, where contextual factors (treatment administration, population characteristics, healthcare system characteristics) are fixed and balanced across the two (or more) study groups through randomisation, blinding and standardisation.	WHO CC PPRI (2024) and YHEC (2025) adapted by ASCERTAIN consortium
Encryption	A process of converting data into a code to prevent unauthorized access.	ASCERTAIN consortium
ePrivacy	European Union directive governing the protection of personal data in electronic communications.	ASCERTAIN consortium
Ethical Data Management	The practice of managing data in a way that respects individual rights and ethical standards.	Access2Meds
European health values	A set of common values that underpin European health systems as stated by the Council of the European Union. These values include universality, access to good quality care, equity, and solidarity	European Commission (2006)

Term	Definition	Source
European Medicine Agency (EMA)	The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU). It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. EMA protects public and animal health in EU Member States, as well as the countries of the European Economic Area, by ensuring that all medicines available on the EU market are safe, effective and of high quality.	Windisch (2022)
European Union (EU)	The European Union (EU) was established in 1992 by the Maastricht Treaty and is an economic and political partnership between 27 democratic European states. The EU has its own institutions that govern the EU and enact its laws.	Windisch (2022)
FAIR (findable, accessible, interoperable, and reusable) data principles	Data that is Findable, Accessible, Interoperable, and Reusable. FAIR emphasizes the importance of clear metadata, open standards, and easy access to facilitate data sharing and reuse across different disciplines and platforms. By following FAIR principles, researchers ensure that their data is well-organized, machine-readable, and accessible to others for validation and further analysis.	Wilkinson et al. (2016)
GDPR (General Data Protection Regulation)	European Union regulation that governs the protection of personal data.	European Commission (2016)

Term	Definition	Source
Gene and cell therapy	Gene and cell therapy is the use of genes and cells to treat disease. Gene therapy is the use of genetic material to treat genetic diseases. This may involve adding a wild type copy of the gene (gene addition) or altering a gene with mutation to the wild type gene (gene editing). The treatment may take place outside of the body (ex vivo) or inside the body (in vivo). To get the gene into the genome inside the cells, modified viruses or other vectors are used. Cell therapy is the use of cells that are taken either from the patient themselves or a donor to treat diseases. Cells used for cell therapy are often stem cells, cells that can mature into different types of specialised cells. Cells used for cell therapy may or may not be genetically altered. It is sometimes easier to remove cells from the body, treat them with gene therapy and then place them back than treating the cells inside the body. This is the case for gene therapy for blood disorders. Gene and cell therapy therefore often go together, which is reflected in the name of our society.	ESGCT (2025)
Genetic testing	Genetics refers to genes and their roles in inheritance – in other words, the way that certain traits or conditions are passed down from one generation to another. Genetics involves scientific studies of genes and their effects. Genes (units of heredity) carry the instructions for making proteins, which direct the activities of cells and functions of the body.	National Human Genome Research Institute (2018)

Term	Definition	Source
Genomic profiling	Genomics refers to the study of all of a person's genes, i.e. the genome, including interactions of genes with each other and with the environment. For complex diseases that are typically caused by a combination of environmental and genetic factors, for example heart disease, asthma and diabetes, genomics are used to understand and characterize those diseases, potentially offering new possibilities for diagnosis and treatment. Genomic profiling refers specifically to the laboratory methods used to learn about genomics, using samples of tissue, blood or other bodily fluids. For example, genomic profiling can be used on samples from tumor tissue to identify mutations or other genomic alterations in a tumor's DNA. Learning about tumor genomics can help in the the diagnosis, treatment selection and prevention of cancer Laboratory methods for genomic profiling include whole-genome sequencing, whole-exome sequencing, (targeted) gene panel sequencing, among others, see also the entry for next-generation sequencing.	National Human Genome Research Institute (2018) NCI (2024)
Green manufacturing	Green manufacturing refers to a production process that reduces the overall carbon footprint in order to minimize its environmental impact and recover resources.	adapted from Dornfeld (2013)
Health care provider / health care professional	An organisation or person who delivers proper health care in a systematic way professionally to any individual in need of health care services.	WHO CC PPRI (2024)
Health institution	An organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.	European Parliament/Council of the European Union (2017a) European Parliament/Council of the European Union (2017b)

Term	Definition	Source
Health-related quality of life (HRQoL)	Health-related quality of life (HRQoL) considers many different aspects related to a person's perception of quality of life affected by health status. These include physical, psychological, functional, and social aspects. HRQoL can be measured using different scales, where an individual's health status is assessed on a scale from 0 to 1, where 0 refers to death and 1 to perfect health.	EUPATI (2025) adapted by ASCERTAIN Consortium
Health technology	A medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.	European Parliament/Council of the European Union (2011)
Health technology assessment (HTA)	Health technology assessment or 'HTA' means a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.	European Parliament/Council of the European Union (2021)
HORIZON Europe	Horizon Europe is the European Union's key funding programme for research and innovation. The programme facilitates collaboration and strengthens the impact of research and innovation in developing, supporting and implementing EU policies while tackling global challenges. It supports creating and better dispersing of excellent knowledge and technologies.	European Commission (2024)
Incremental cost-effectiveness ratio (ICER)	Incremental cost-effectiveness ratio, defined by the differences in cost between intervention and comparator relative to differences in health gain (often measured in QALYs).	Briggs (2006)
Informed Consent	The process by which a participant confirms their voluntary willingness to take part in a study after being informed of all the relevant details.	ASCERTAIN consortium
Innovation	Innovation is the use of new ideas, products or methods where they have not been used before. Innovations are based on the results of new technological developments, new technology combinations, or the use of other knowledge, acquired by the enterprise.	European Commission (2024)

Term	Definition	Source
Innovative health technology (IHT)	Health technology which has the potential to improve health outcomes and quality of life, or to offer a solution to an unmet medical/health technology need. The ASCERTAIN project prefers the term potentially innovative health technology (pIHT) for products where the therapeutic benefit has not (yet) been established.	WHO (2024) adapted by ASCERTAIN consortium
Integrity	The property that information is accurate and complete.	ASCERTAIN Consortium
In vitro diagnostic medical device (IVD)	Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: a) concerning a physiological or pathological process or state; b) concerning congenital physical or mental impairments; c) concerning the predisposition to a medical condition or a disease; d) to determine the safety and compatibility with potential recipients; e) to predict treatment response or reactions; f) to define or monitor therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.	European Parliament/Council of the European Union (2017b)

Term	Definition	Source
List price	The price that suppliers display as the price at which they are prepared to sell their product and/or regulated by legislation. A list price is quoted and/or indicated in a purchaser's price list, a catalogue, on an internet site, in advertisements, in a national price list/formulary or similar. A list price may differ from the actual transaction price. Depending on the country and/or the product, they may or may not include delivery and installation costs, value-added tax/VAT and other indirect taxes on products, discounts, surcharges and rebates, invoiced service charges and voluntary gratuities.	WHO CC PPRI (2024)
Managed entry agreements (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financial-based agreements, which focus only on the price (reward for manufacturers), through discounts, rebates, or expenditure caps; and performance-based agreements which links the price to health outcomes.	WHO CC PPRI (2024)
Manufacturer (MF) of a medical device or IVD	A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark.	European Parliament/Council of the European Union (2017a) European Parliament/Council of the European Union (2017b)
Market access	Market access refers to the process of ensuring that treatments (medicines, medical devices etc.) for which marketing authorisation has been obtained from regulatory authorities are available (reimbursed, funded) to all patients who may benefit.	YHEC (2025)

Term	Definition	Source
Medical device (MD)	Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: o diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, o diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, o investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state, o providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: o devices for the control or support of conception o products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.	European Parliament/Council of the European Union (2017a)
Medicinal product	A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action. Note that ASCERTAIN Consortium prefers the term “medicinal product” over “pharmaceutical”, “medicine”, or “drug”, as it includes advanced therapeutic medicinal products, such as cell and gene therapies.	European Medicines Agency (2024)

Term	Definition	Source
Modifiers	Modifiers are characteristics that decision makers can use to vary the level of the cost-effectiveness threshold. These characteristics could be related to the intervention, the specific medical condition(s), or the targeted population.	Griffiths et al. (2015) Zhang/Garau (2020) adapted by ASCERTAIN Consortium
Net health benefit (NHB)	Net health benefit - defined by the difference in incremental effect and incremental costs relative to CET.	Briggs (2006)
Net monetary benefit (NMB)	Net monetary benefit - defined by the differences in incremental effect multiplied with CET and incremental costs.	Briggs (2006)
Net price	The amount actually received by the supply chain actors (i.e. manufacturer, wholesale, pharmacy retail), after subtracting rebates, discounts and any other incentives.	Perehudoff et al. (2021)
Next-generation sequencing (NGS)	A high-throughput method used to determine part of the nucleotide sequence of an individual's genome. This technique utilizes DNA sequencing technologies that are capable of processing multiple DNA sequences in parallel. Also called massively parallel sequencing and NGS NGS technologies are used clinically for whole genome sequencing (WGS), whole exome sequencing (WES), gene panel testing and increasingly for single gene testing.	NCI (2024)
Notified body (NB)	A conformity assessment body designated in accordance with MDR/IVDR.	European Parliament/Council of the European Union (2017a) European Parliament/Council of the European Union (2017b)

Term	Definition	Source
Opportunity cost for an intervention	The opportunity cost of an intervention is what is foregone as a consequence of adopting a new intervention. In a fixed budget health care system where increased costs will displace other health care services already provided, the opportunity cost is measured as the health lost as a result of the displacement of activities to fund the selected intervention. In terms of choosing to fund intervention A over intervention B, the opportunity cost of choosing A would be the potential value or the difference (incremental benefits) of A compared to B and the difference in cost (incremental cost) of A compared to B. Often, when a new costly intervention is adopted within a health system, the opportunity cost (i.e. the health benefits displaced) will be unknown and unrelated to the intervention being adopted.	YHEC (2025)
Patient	Any natural person who seeks to receive or receives healthcare in a Member State.	European Parliament/Council of the European Union (2011)
Payer	Public or private organisation that pays or insures health or medical expenses on behalf of beneficiaries or recipients. Recipients pay a premium for this coverage in all private and some public programs of social insurance, while the system is supported by general taxation in the National Health Services. The payer then pays bills on behalf of covered individuals, which are called third party payments. They are distinguished by the separation among the individual receiving the service (the first party), the individual or institution providing it (the second party), and the organisation paying for it (third party).	WHO CC PPRI (2024)
Personal Data	Any information relating to an identified or identifiable natural person.	European Commission (2016)

Term	Definition	Source
Perspective	In health economics, the perspective applied in an analysis defines which cost components should be included, where the two main perspectives are healthcare and societal.	Briggs (2006) Sanders et al. (2016) adapted by ASCERTAIN Consortium
Pharmaceutical	see "Medicinal product"	
Policy maker	A person or institution that is involved in policy development and formulation (e.g. national governments, public authorities).	Windisch (2022)
Precision cancer medicine (PCM)	Precision medicine is the tailoring of medical treatment to the individual characteristics of each patient and his or her disease.	AACR (2024)
Price	Generally, the price is the amount of money given by the buyer to the seller in exchange for a good or service. For medicinal products, different buyers pay different prices and to different sellers along the supply chain. Therefore, the price type (i.e. the stage in the supply chain to which a price applies) needs to be specified. Common price types include: • ex-factory price, • pharmacy purchasing price, • pharmacy retail price. In addition, a distinction needs to be made between net (after deduction of discounts) and gross price (usually referred to as "price"). See also "list price" and "net price" in this glossary.	Asmundson (2013) and WHO CC PPRI (2024) adapted by ASCERTAIN Consortium
Price determinant	Inputs and parameters linked to a health technology for the calculation of a health technology's price, considered by stakeholders (health technology developer, healthcare payers, policy- and decision-makers, patients, health care professionals, and investors).	ASCERTAIN Consortium
Price model	A model for calculating the price of a health technology based on a set of defined model inputs and parameters.	ASCERTAIN Consortium

Term	Definition	Source
Pricing	Action by a government authority to set the price of a medicine and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it.	WHO CC PPRI (2024)
Pricing policy	Regulations and actions taken by government authorities to set the price of a medicine as part of exercising price control. Strategies by private sector actors (e.g. pharmaceutical industry and supply chain actors) to determine and set a medicine price are not subsumed under the term "policy".	WHO CC PPRI (2024)
Probabilistic analysis (PA)	Probabilistic analysis, where all uncertainty in model parameters are accounted for to estimate expected costs and QALYs of each intervention.	Briggs (2006)
Pseudonymization	The process of using artificial identifiers (pseudonyms) to replace personally identifiable information.	ASCERTAIN Consortium
QALY	Quality adjusted life years, which is defined as a combination of HRQoL (see above) and time. One year in perfect health is equal to 1 QALY.	Briggs (2006)
Randomised controlled trial (RCT)	In randomised controlled trials, patients (or clusters of patients) are randomly assigned to either the active treatment or the control arm. Usually, large numbers of patients are included for these trials to generate robust data on the efficacy of a treatment.	European Medicines Agency (2024)

Term	Definition	Source
Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices (Medical Device Regulation, MDR)	The MDR came into force on 25 May 2017 and, after a four-year transition period, has replaced the two EU Directives 90/385/EEC and 93/42/EEC with effect from 26 May 2021. Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The aim of the Regulation: o It updates the rules on placing, making available and putting into service medical devices* for human use and their accessories on the European Union (EU) market. o It also contains rules on how clinical investigations* concerning such devices and accessories are carried out in the EU. o It aims to improve patient safety by introducing more stringent procedures for conformity assessment (to ensure that unsafe or non-compliant devices do not end up on the market) and post-market surveillance.	European Parliament/Council of the European Union (2017a)
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (In Vitro Diagnostics Regulation, IVDR)	The IVDR entered into force on 25 May 2017 and replaced EU Directive 98/79/EC after a five-year transitional period with an effective date of 26 May 2022. The purpose of the Regulation: o The Regulation updates the rules for the placing on the market, making available on the market of the European Union (EU) and putting into service of in vitro diagnostic medical devices and their accessories intended for human use. o The Regulation also lays down rules concerning performance studies carried out in the EU on in vitro diagnostic medical devices (or their accessories). o The aim is to improve patient safety by introducing stricter procedures for conformity assessment (to ensure that unsafe or non-compliant products are not placed on the market) and post-market surveillance.	European Parliament/Council of the European Union (2017b)

Term	Definition	Source
Regulators / regulatory bodies	A medicines or medical devices regulatory body is a governmental body with the authority to grant licenses or authorisations required for marketing a new medicinal product or medical device in a jurisdiction.	ASCERTAIN Consortium
Reimbursement / payment / funding	Coverage of the cost of reimbursable medicines or medical devices by a public payer (such as social health insurance / National Health Service).	WHO CC PPRI (2024) adapted by ASCERTAIN Consortium
Right of Access	The right to obtain confirmation from the data controller as to whether or not personal data concerning them is being processed, and access to that data.	European Commission (2016)
Right to Data Portability	The right to receive personal data concerning them in a structured, commonly used, and machine-readable format and to transmit those data to another controller.	European Commission (2016)
Right to Erasure (Right to be Forgotten)	The right to obtain from the data controller the erasure of personal data concerning them without undue delay.	European Commission (2016)
Right to Information	The right to be informed about how one's personal data is processed.	European Commission (2016)
Right to Object	The right to object at any time to the processing of personal data concerning them based on their particular situation.	European Commission (2016)
Right to Rectification	The right to obtain from the data controller the correction of inaccurate personal data concerning them without undue delay.	European Commission (2016)
Right to Restriction of Processing	The right to obtain from the data controller restriction of processing under certain circumstances.	European Commission (2016)

Term	Definition	Source
Risk classes for in vitro diagnostic medical devices	The classification according to risk classes is based on the classification rules in Annex VIII of the IVDR. The application of the classification rules depends on the intended purpose of the products: o Class A o Class B o Class C o Class D Class A products have a low risk, Class D products have a high risk.	European Parliament/Council of the European Union (2017b)
Risk classes for medical devices	The classification according to risk classes is based on the classification rules in Annex VIII of the MDR. The application of the classification rules depends on the intended purpose of the devices: o Class I › Class I medical devices with a measuring function (Class Im) › Class I sterile medical devices (Class Is) › Reusable surgical instruments of class Ir o Class IIa o Class IIb o Class III Class I products have a low risk, Class III products have a high risk.	European Parliament/Council of the European Union (2017a) MDCG 2021 MDCG 2022
Scatterplot	An incremental cost-effectiveness (ICE) scatterplot visualizes uncertainty in the incremental cost-effectiveness between two interventions. Each point represents a simulation's incremental cost (y-axis) vs. incremental effectiveness (x-axis) on a cost-effectiveness plane divided into quadrants (e.g., more costly/more effective in the Northeast quadrant). A CET threshold line highlights cost-effective outcomes.	Briggs (2006)

Term	Definition	Source
Societal value	In health economic evaluation, societal value means components beyond health impacts to the treated individual and costs beyond those incurred by the healthcare sector to deliver those interventions, such as consumption, economic activity, education, environment, family spillover (i.e., informal caregiver burden), healthcare system capacity, housing, legal, social services, and transportation. Societal value can also be reflected in pricing policies through productivity gains and losses and the impact on informal carers.	Breslau et al. (2023); Paris/Belloni (2013) adapted by ASCERTAIN Consortium
Stakeholder	A person or organisation with a legitimate interest in a topic related to health care. Stakeholders include the following: • pharmaceutical manufacturers, • medical device manufacturers, • patient organisations, • organisations representing health care professionals, • other health care organisations, • payers, • HTA bodies, • civil society organisations, • investors, and • academia.	WHO CC PPRI (2024) adapted by ASCERTAIN Consortium
Supply-side Cost-effectiveness threshold	Supply-side cost-effectiveness thresholds are thresholds which are determined based on an approach that suggests that healthcare resource allocation should be guided by the principle of opportunity cost. When resources are reallocated, new investments displace existing services, so the CET should reflect the value of the health benefits forgone by the best alternative use of the resources.	Sampson et al. (2022) Garrison et al. (2019)
Sustainability	Ability to meet present needs without compromising ability to meet future needs.	WHO CC PPRI (2024)
Time horizon	The time period for which health outcomes and costs are applicable to in an economic evaluation.	ASCERTAIN Consortium

Term	Definition	Source
Unmet medical / health technology need (UN)	Unmet medical / health technology needs means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment in the Union or, even if such a method exists, in relation to which the medicinal product / health technology concerned will be of major therapeutic advantage to those affected.	European Commission (2006) adapted by ASCERTAIN Consortium
Value-based pricing	Through this policy authorities set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated. The price and reimbursement decision is taken jointly based on a value assessment.	WHO CC PPRI (2024)
Value of information (VoI) analysis	VoI analysis in economic evaluation assesses the potential benefit of acquiring additional information before making a decision, especially when there is uncertainty in the data. It helps determine whether further research or data collection is worth the cost, by quantifying how much uncertainty impacts the decision-making process and outcomes. VOI analysis aids in prioritizing research investments by identifying where new information could lead to more efficient or effective healthcare decisions.	Briggs (2006)

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