

Core area	Outcome domain	Explanation
Death	1. Mortality/survival	Includes overall (all-cause) survival/mortality and cause-specific survival/mortality, as well as composite survival outcomes that include death (e.g. disease-free survival, progression-free survival, amputation-free survival)
Physiological/ clinical	<b>Physiological/clinical</b> 2. Blood and lymphatic system outcomes 3. Cardiac outcomes 4. Congenital, familial and genetic outcomes 5. Endocrine outcomes 6. Ear and labyrinth outcomes 7. Eye outcomes 8. Gastrointestinal outcomes 9. General outcomes 10. Hepatobiliary outcomes 11. Immune system outcomes 12. Infection and infestation outcomes 13. Injury and poisoning outcomes 14. Metabolism and nutrition outcomes 15. Musculoskeletal and connective tissue outcomes 16. Outcomes relating to neoplasms: benign, malignant and unspecified (including cysts and polyps) 17. Nervous system outcomes 18. Pregnancy, puerperium and perinatal outcomes 19. Renal and urinary outcomes 20. Reproductive system and breast outcomes 21. Psychiatric outcomes 22. Respiratory, thoracic and mediastinal outcomes 23. Skin and subcutaneous tissue outcomes	<p>Physiological/clinical outcomes include measures of physiological function, signs and symptoms, as well as laboratory (and other scientific) measures relating to physiology, and are categorised according to the underlying cause/body system.</p> <p><i>General</i> outcomes include those affecting the whole body which cannot be attributed to a certain body system e.g. fatigue, chills, flu like symptoms, malaise, anorexia, pain (unspecified, not associated with a particular body system), fever (not attributable to infection), anthropometric measures (e.g. weight), “global” measures, “symptoms” (not associated with a particular body system), “physical health”, fitness.</p> <p>Pain outcomes are categorised according to underlying cause or body system or within the <i>General</i> outcomes domain (if non-specific).</p> <p>Laboratory parameters (for example, from blood samples) and scientific measures (for example, pharmacokinetic outcomes) should be classified within the physiological domain that captures the reason for the assessment (rather than within the <i>Blood and lymphatic system</i> domain, for example).</p> <p><i>Psychiatric</i> outcomes include all those relating to mental health conditions and associated behaviours (e.g. addictions and behavioural problems).</p> <p><i>Pregnancy, puerperium and perinatal domain</i> extends to outcomes relating to breastfeeding and weaning.</p> <p><i>Outcomes relating to neoplasms</i> include those related to non-solid and solid tumours.</p> <p>Sleep outcomes which relate to clinical signs, symptoms, or lab measures may be classified as <i>Nervous system, Psychiatric</i> or <i>Metabolism and nutrition</i> outcomes, depending on cause. However, outcomes</p>

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	24. Vascular outcomes	relating to the impact of sleep deprivation, for example, should instead be classified within the relevant functioning domain.
<b>Life impact</b>	<b>Functioning</b> 25. Physical functioning 26. Social functioning 27. Role functioning 28. Emotional functioning/wellbeing 29. Cognitive functioning	<p><b>Impact outcomes</b></p> <p><i>Physical functioning:</i> impact of disease/condition on physical activities of daily living (for example, ability to walk, independence, self-care, performance status, disability index, motor skills, sexual dysfunction, health behaviour and management)</p> <p><i>Social functioning:</i> impact of disease/condition on social functioning (e.g. ability to socialise, behaviour within society, communication, companionship, psychosocial development, aggression, recidivism, participation)</p> <p><i>Role functioning:</i> impact of disease/condition on role (e.g. ability to care for children, work status)</p> <p><i>Emotional functioning/wellbeing:</i> impact of disease/condition on emotions or overall wellbeing (e.g. ability to cope, worry, frustration, confidence, perceptions regarding body image and appearance, psychological status, stigma, life satisfaction, meaning and purpose, positive affect, self-esteem, self-perception and self-efficacy)</p> <p><i>Cognitive functioning:</i> impact of disease/condition on cognitive function (e.g. memory lapse, lack of concentration, attention); outcomes relating to knowledge, attitudes and beliefs (e.g. learning and applying knowledge, spiritual beliefs, health beliefs/knowledge)</p>
	30. Global quality of life	Includes only implicit composite outcomes measuring global quality of life
	31. Perceived health status	Subjective ratings by the affected individual of their relative level of health
	32. Delivery of care	Includes outcomes relating to the delivery of care, including <ul style="list-style-type: none"> <li>• adherence/compliance</li> <li>• patient preference</li> <li>• tolerability/acceptability of intervention</li> <li>• withdrawal from intervention (e.g. time to treatment failure)</li> <li>• appropriateness of intervention</li> </ul>

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		<ul style="list-style-type: none"> <li>• accessibility, quality and adequacy of intervention</li> <li>• patient/carer satisfaction (emotional rather than financial burden)</li> <li>• process, implementation and service outcomes (e.g. overall health system performance and the impact of service provision on the users of services)</li> </ul>
	33. Personal circumstances	Outcomes relating to patient's finances, home and environment
<b>Resource use</b>	<b>Resource use</b> 34. Economic 35. Hospital 36. Need for further intervention 37. Societal/carer burden	<p><i>Economic:</i> general outcomes (e.g. cost, resource use) not captured within other specific resource use domains</p> <p><i>Hospital:</i> outcomes relating to inpatient or day case hospital care (e.g. duration of hospital stay, admission to ICU)</p> <p><i>Need for further intervention:</i> outcomes relating to medication (e.g. concomitant medications, pain relief), surgery (e.g. caesarean delivery, time to transplantation) and other procedures (e.g. dialysis-free survival, mode of delivery)</p> <p><i>Societal/carer burden:</i> outcomes relating to financial or time implications on carer or society as a whole (e.g. need for home help, entry to institutional care, effect on family income)</p>
<b>Adverse events</b>	38. Adverse events/effects	Includes outcomes broadly labelled as some form of unintended consequence of the intervention (e.g. adverse events/effects, adverse reactions, safety, harm, negative effects, toxicity, complications, sequelae). Specifically named adverse events should be classified within the appropriate taxonomy domain above with an additional level of categorisation which identifies that this outcome is being considered as an adverse event.