

Clinical readiness for patient-customised therapies

Assessment tool: instructions for use

This tool provides a structured assessment of whether the institutional capabilities required to deliver a patient-customised therapy are in place, assigned to accountable personnel, supported by evidence and sustainable. Each indicator is evaluated across four maturity levels: not established, initiated, developing and established. Clinical readiness is achieved when all applicable indicators meet the established threshold.

Maturity levels

Level	Label	Definition
1	Not established	No capability, process, personnel or documentation is in place for this indicator.
2	Initiated	Requirements have been identified and responsibilities assigned, but the capability is not yet operational or documented.
3	Developing	The capability is drafted or partly implemented; specified elements remain incomplete, unapproved or unconfirmed.
4	Established	The capability is approved, documented, resourced and operational, with responsibilities and records in place.
N/A	Not applicable	The indicator does not apply to this therapy, patient or site. State the reason in the rationale column.

Assessment record

Institution / site	
Patient or programme identifier	
Therapy and modality	
Assessor(s) and role	
Assessment date	
Planned review date	
Treatment authorised (yes / no)	

Domains in this tool

Domain	Title	Subdomains	Indicators
Domain 1	Disease expertise	Diagnosis and eligibility	2
Domain 2	Pharmaceutical expertise	Team capability; Product management; Medication readiness	6
Domain 3	Clinical delivery capability	Administration; Emergency and procedural capability; Specialist availability	6
Domain 4	Governance and regulatory oversight	Approvals and accountability; Quality and inter-service governance; Operational readiness; Financial readiness	7
Domain 5	Patient partnership and supportive care	Education and consent; Individualised planning and safety; Equity and practical support	10
Domain 6	Treatment monitoring	Outcome definition and baseline; Monitoring plans and pathways; Multidisciplinary review and treatment decisions; Pharmacovigilance	7
Domain 7	Evidence governance and collaborative learning	Data management and quality assurance; Collaborative learning networks	4

Glossary

Definitions used in the clinical readiness assessment tool.

Term	Definition
Adverse event	Any unfavourable or unintended medical occurrence in a patient receiving an intervention, whether or not the event is considered to be caused by the intervention.
Chain of custody	The documented and traceable record of the collection, handling, transfer, processing, storage and disposition of a biological sample or therapeutic product.
Chain of identity	The continuous and verifiable link between an individual patient and their biological sample, associated data and, where applicable, a patient-specific therapeutic product throughout the clinical pathway.
Clinical outcome measure	A standardised measure used to assess a patient's health status, symptoms, function, survival or other clinically meaningful outcomes, including changes in these outcomes over time.
Clinical readiness	The preparedness of an institution and clinical team to safely, effectively and sustainably deliver a therapy and evaluate its outcomes. Within this tool, clinical readiness encompasses seven domains: disease expertise; pharmaceutical expertise; clinical delivery capability; governance and regulatory oversight; patient partnership and supportive care; treatment monitoring; and evidence governance and collaborative learning.
Competency training	Training that includes documented assessment demonstrating that an individual has the knowledge, skills and ability required to safely and correctly perform a specified clinical or operational task.
Disease mechanism	The biological processes through which a disease develops or causes its clinical manifestations, including the relationship between the underlying molecular abnormality and the disease phenotype where this is known.
Efficacy endpoint	A pre-specified outcome or measure used to assess whether, and to what extent, an intervention achieves a defined therapeutic or biological effect.
Indicator	A defined and assessable criterion used within this tool to determine the level of readiness achieved for a specific component of clinical delivery.

Instructions for use (continued)

Term	Definition
Institution	The healthcare, academic or other organisation responsible for, or materially involved in, the clinical delivery and oversight of the therapy being assessed.
Maturity level	A defined level representing the extent to which the capabilities, processes, infrastructure and evidence required for clinical readiness have been established and demonstrated.
Minimal clinically important difference	The smallest change in a clinical outcome measure that is considered meaningful to patients or that represents a clinically important change in health status.
Molecular diagnosis	Identification of the molecular alteration or mechanism responsible for, or contributing to, a patient's disease using an appropriately validated diagnostic method.
Molecular outcome measure	A measure of a molecular or cellular characteristic used to assess biological change associated with disease progression or response to an intervention.
Multidisciplinary team	A group of professionals with complementary clinical, scientific and/or operational expertise who collectively contribute to decisions about patient assessment, treatment, delivery and follow-up.
Natural history	The course of a disease over time in the absence of the intervention being evaluated, including its onset, progression, variability, complications and clinical outcomes.
Patient-customised therapy	A therapeutic intervention that is specifically designed, selected or manufactured for an individual patient on the basis of that patient's molecular, biological or other disease characteristics.
Patient-reported outcome measure (PROM)	A standardised measure used to capture a patient's report of their health, symptoms, functioning, quality of life or treatment experience without interpretation by a clinician or other observer.
Pharmacovigilance	The processes used to detect, assess, understand, document and respond to adverse effects and other safety issues associated with the use of a therapeutic intervention.
Principal investigator	The individual with overall responsibility for the conduct of a clinical study at a study site, including oversight of participant safety, protocol compliance and the integrity of study data.
Rescue medication	A medication or treatment specified in advance for use when required to manage acute symptoms, treatment-related effects or clinical deterioration that cannot appropriately await routine management.
Safety outcome assessment	A pre-specified assessment or measure used to identify, characterise and evaluate adverse events, toxicities or other potential harms associated with an intervention.
Standard operating procedure (SOP)	A controlled written document specifying the procedures and responsibilities required to perform a clinical, laboratory or operational activity consistently, safely and in accordance with applicable requirements.
Subdomain	A defined component of one of the clinical readiness domains that groups related indicators addressing a specific aspect of readiness.
Therapeutic eligibility	The clinical, molecular and other pre-specified criteria used to determine whether a patient is an appropriate candidate to receive a particular therapeutic intervention.
Translational checkpoint	A pre-specified decision point at which defined evidence and readiness criteria are evaluated to determine whether a therapy or programme should progress to the next stage of clinical translation.

Domain 1: Disease expertise					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 1	Diagnosis and eligibility	The clinical and molecular diagnosis and therapeutic eligibility are confirmed through multidisciplinary review.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The genetic diagnosis and the predefined therapeutic eligibility considerations have been reviewed by the immediate diagnostic team, but formal multidisciplinary review has not been completed.		
			3. Developing: A formal review process is underway, but assessment of the predefined eligibility considerations, or input from all relevant disciplines, remains incomplete.		
			4. Established: A documented multidisciplinary review has confirmed the genetic diagnosis and assessed all predefined therapeutic eligibility considerations, with responsible experts, conclusions and the final eligibility decision recorded in detail.		
		The disease mechanism and relevant natural-history evidence are characterised and collated to inform eligibility, modality selection and monitoring.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Available evidence is reviewed for the individual patient, but the approach is informal and responsibilities are not clearly assigned.		
			3. Developing: A documented approach is used to characterise disease mechanism and natural history, but evidence sources, multidisciplinary interpretation or application to treatment planning remains incomplete.		
			4. Established: Disease mechanism and relevant natural-history evidence are systematically characterised and documented by appropriately qualified personnel, and are used to inform eligibility, modality selection and outcome measurement.		

Domain 2: Pharmaceutical expertise					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 2	Team capability	The team has demonstrated competence in the pharmacology, formulation, dosing, administration and safety of the proposed modality.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Responsible experts have been assigned, but education, training and individual responsibilities have not been fully defined.		
			3. Developing: Relevant experts have been educated, but assessment of competence, responsibilities or availability across the treatment period remains incomplete.		
			4. Established: Relevant experts have documented competence in the proposed therapeutic, defined responsibilities and confirmed availability throughout treatment. Supporting resources on the modality and its appropriate use are collated for the wider clinical team, including drug name(s), mechanism of action and pharmacokinetic parameters.		
	Product management	Safe product-release, handling and storage procedures are established within defined timelines.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Product-specific handling and storage requirements have been defined by experts, but the procedures and timelines for handling and storage have not been finalised.		
			3. Developing: Handling and storage procedures have been drafted, but availability of equipment, documentation or contingency arrangements remains incomplete.		
			4. Established: Approved procedures define product receipt, verification, recording, storage, preparation and transfer, with trained experts assigned to individual tasks, an accountability system prepared and contingency arrangements included.		

Domain 2: Pharmaceutical expertise					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		Chain of identity and chain of custody are maintained throughout product delivery.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Critical product transfer points and responsible experts have been identified, and processes for documenting receipts, ordering, dispensing, product identity and custody are being developed.		
			3. Developing: Chain-of-identity and chain-of-custody procedures are documented, but tracking, verification, handover documentation or reconciliation remains incomplete.		
			4. Established: Product identity and custody are consistently verified and documented at every critical transfer point, with defined responsibilities, complete records and procedures for investigating discrepancies.		
		The patient-specific dose, regimen and safety plan are informed by available evidence and by review of the patient's clinical and genomic data, and are verified before administration.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Relevant evidence, health records, genomic findings and other patient data have been identified, and expert review has begun.		
			3. Developing: Available evidence and patient data have been partly reviewed, but their integration into the dose, regimen or risk assessment remains incomplete.		
			4. Established: A multidisciplinary review has integrated available evidence with the patient's health records, clinical evaluations, genomic findings and concomitant medications. The resulting dose, regimen and safety plan have been independently verified, documented and authorised.		

Domain 2: Pharmaceutical expertise					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Medication readiness	Required supportive medications are prepared and available before treatment.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required supportive medications have been identified, and prescribing, procurement or preparation arrangements have begun.		
			3. Developing: Supportive medications have been prescribed or ordered, but dose verification, preparation, timing, availability or administration responsibilities remain incomplete.		
			4. Established: All required supportive medications have been prescribed, independently verified, prepared and made available before treatment, with administration timing and responsibilities documented.		
		Required rescue medications are immediately available at the treatment location.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required rescue medications have been identified and ordered, and their storage location and administration responsibilities are being planned.		
			3. Developing: Rescue medications have been obtained, but immediate accessibility, patient-specific dose verification and documentation of drug interactions remain incomplete.		
			4. Established: Required rescue medications are immediately accessible at the treatment location, with verified patient-specific doses, confirmed drug interactions, inventory records and clearly documented administration responsibilities.		

Domain 3: Clinical delivery capability					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 3	Administration	Therapy administration protocols are established for the proposed treatment.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The administration route, procedural facilities, administering and anaesthetic experts, equipment, procedural medications, recovery setting and observation requirements have been identified, and protocol development has begun.		
			3. Developing: An administration protocol has been drafted, but pre-dose checks, concomitant medication management, procedural or anaesthetic steps, administration, immediate monitoring, recovery, observation, discharge or escalation criteria, or documentation remain incomplete.		
			4. Established: An approved protocol defines pre-dose checks and medication review, product preparation and verification, required sampling, administration and anaesthesia or analgesia, immediate safety monitoring, recovery, dosing-phase-specific observation periods, discharge and escalation criteria, documentation and responsible experts.		
	Emergency and procedural capability	Management protocols are established for anticipated therapy-specific toxicities.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Anticipated therapy-specific toxicities have been reviewed, and the clinical experts, investigations and treatments required for their management have been identified.		
			3. Developing: Toxicity-management protocols have been drafted, but recognition criteria, assessment measures, grading, rescue interventions or escalation responsibilities remain incomplete.		
			4. Established: Approved protocols define the recognition, assessment, grading and management of anticipated toxicities, with required investigations, medications, responsible personnel and escalation pathways confirmed.		

Domain 3: Clinical delivery capability					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		Emergency management pathways are established for anticipated complications during the peri-treatment and post-dosing period.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Potential peri-treatment emergencies, responsible clinical teams and required escalation services have been identified, and pathway development has begun.		
			3. Developing: Emergency pathways have been drafted, but recognition criteria, responsibilities, immediate management, escalation contacts or transfer arrangements remain incomplete.		
			4. Established: Documented pathways define how anticipated peri-treatment complications are recognised, immediately managed and escalated, with direct contacts, responsible personnel and transfer arrangements confirmed.		
		Required study nursing, resuscitation equipment, and rapid access to laboratory testing and point-of-care services are available where indicated.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required peri-treatment services have been identified, and the relevant departments and responsible personnel have been contacted.		
			3. Developing: Access has been discussed or agreed in principle, but scheduling, urgent access, service responsibilities, patient-specific requirements or contingencies remain incomplete.		
			4. Established: Access to all required peri-treatment services is confirmed, with named contacts, scheduling arrangements, responsibilities and urgent-assessment pathways documented.		

Domain 3: Clinical delivery capability					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Specialist availability	Treating investigators are immediately contactable during treatment and the defined post-treatment period.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Treating investigators and delegated clinical contacts have been identified, and availability arrangements are being developed.		
			3. Developing: Contact details or an availability roster have been drafted, but coverage, handovers, response expectations or escalation arrangements remain incomplete.		
			4. Established: A treating investigator or delegated clinician is immediately contactable throughout the peri-treatment period, with direct contact details, coverage, handover and escalation arrangements documented.		
		Specialist clinical support (nursing, junior medical and specialist) is available 24/7 during the defined treatment and monitoring period.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required specialist services and periods of coverage have been identified, and support arrangements are being discussed.		
			3. Developing: Specialist support is available for some periods, but overnight, weekend, handover, response-time or escalation coverage remains incomplete.		
			4. Established: Documented specialist coverage is in place throughout the defined peri-treatment period, with confirmed rosters, direct contacts, handover procedures, response expectations and escalation responsibilities.		

Domain 4: Governance and regulatory oversight					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 4	Approvals and accountability	Required institutional, ethics and regional regulatory approvals are obtained before treatment.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The required institutional, ethics and regulatory approval pathways have been identified, responsible experts have been assigned, stakeholders have been engaged, and preparation of the applications has begun.		
			3. Developing: Required applications have been prepared or submitted, but some approvals, responses, conditions or institutional authorisations remain outstanding.		
			4. Established: All required institutional, ethics and regulatory approvals have been obtained, approval conditions have been addressed, and authorisation to proceed with treatment is documented.		
		Clinical and organisational accountability is formally assigned.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: A proposed principal investigator, clinical lead and accountable institutional bodies have been identified, and formal appointments and governance arrangements are being developed.		
			3. Developing: Appointments and governance arrangements are provisional, and responsibilities, decision authority, delegation, reporting lines, availability or escalation pathways remain incomplete.		
			4. Established: The principal investigator and clinical lead are formally appointed, and approved governance arrangements define institutional accountability, responsibilities, decision authority, delegation, reporting, availability and escalation pathways throughout treatment and follow-up.		

Domain 4: Governance and regulatory oversight					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Quality and inter-service governance	Standard operating procedures and service-level agreements operationalise post-treatment follow-up and monitoring.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Activities requiring standardised procedures or inter-service agreements have been identified, responsible experts and services have been assigned, and development has begun.		
			3. Developing: Procedures and agreements have been drafted, but responsibilities, service availability, turnaround times, documentation, management of missed assessments or protocol deviations, or escalation processes remain incomplete.		
			4. Established: Approved procedures define how monitoring and follow-up are performed and documented, and service-level agreements define responsibilities, availability, turnaround times and escalation across participating services, including the management of missed assessments and protocol deviations.		
		Quality-management and audit processes are established.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Applicable quality requirements, responsible experts and the required controlled documents have been identified, and development has begun.		
			3. Developing: Quality procedures are partly implemented, but document control, staff training, deviation management, corrective actions, record-keeping or audit arrangements remain incomplete.		
			4. Established: An operational quality-management system comprises current procedures, controlled documents, training records, deviation and corrective-action processes, complete records and a defined audit schedule.		

Domain 4: Governance and regulatory oversight					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Operational readiness	The treatment timeline and initiation are planned and coordinated with manufacturing and product-release timelines.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Key manufacturing, product-release and treatment milestones have been identified, responsible experts have been assigned, and preliminary scheduling has begun.		
			3. Developing: Manufacturing and clinical schedules have been exchanged, but dependencies, product-release timing, patient scheduling or contingency arrangements remain unconfirmed.		
			4. Established: A confirmed day-by-day integrated timeline coordinates manufacturing, product release, transport, facility availability and treatment scheduling, with communication and contingency arrangements documented.		
		Access to an operating theatre or procedural suite is confirmed where required.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The need for an operating theatre or procedural suite has been confirmed, the required clinical services have been identified, and access has been requested.		
			3. Developing: Access has been provisionally arranged, but the procedure date, personnel, anaesthesia, equipment, facility requirements or contingency arrangements remain incomplete.		
			4. Established: Access to the required operating theatre or procedural suite is booked and confirmed, with the procedure date, personnel, equipment, anaesthesia and contingency arrangements documented.		

Domain 4: Governance and regulatory oversight					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Financial readiness	Funding is secured across the required translational, treatment and follow-up activities.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required cost categories, potential funding sources and responsible personnel have been identified, and preparation of budgets or funding applications has begun.		
			3. Developing: Funding has been secured for some activities, but gaps remain across development, manufacture, treatment delivery, monitoring or long-term follow-up.		
			4. Established: Funding is confirmed for all required translational, manufacturing, treatment and follow-up activities, with approved budgets, payment responsibilities and financial contingency arrangements documented.		

Domain 5: Patient partnership and supportive care

Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 5	Education and consent	The patient and caregivers receive comprehensive and timely therapy-specific education.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Responsible personnel have been assigned, therapy-specific educational requirements and appropriate materials have been identified, and education sessions have been scheduled with the patient and caregivers.		
			3. Developing: Education has begun but understanding remains incomplete. The relevant educational materials, and language-support professionals where necessary, have been identified.		
			4. Established: Comprehensive therapy-specific education has been completed using accessible and culturally appropriate information, and patient and caregiver understanding has been assessed and documented.		
		Potential benefits, risks, uncertainties and available alternatives are discussed and documented.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Available evidence on potential benefits, risks, uncertainties and alternative options has been collated, and responsibility for discussing these with the patient has been assigned.		
			3. Developing: Benefits, risks, uncertainties and alternatives have been discussed, but some information, patient questions, assessment of understanding or documentation remains incomplete.		
			4. Established: A balanced discussion of potential benefits, risks, uncertainties, the investigational nature of treatment and available alternatives has been completed and documented, and patient understanding has been confirmed.		

Domain 5: Patient partnership and supportive care					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		Shared decision-making and informed consent are completed before treatment.	1. Not established: No capability, process, personnel or documentation is in place for this indicator. 2. Initiated: Responsible experts, consent requirements and the relevant consent documents have been identified, and shared decision-making discussions have been scheduled with the patient. 3. Developing: Shared decision-making and consent discussions have begun, but patient questions, expectations, decision-making capacity, caregiver involvement or documentation remains incomplete. 4. Established: Shared decision-making has been completed, the patient has had time and opportunity to consider the information and ask questions and has described their expectations for treatment, and valid informed consent is documented before treatment.		
	Individualised planning and safety	An individualised treatment and follow-up plan is agreed with the patient.	1. Not established: No capability, process, personnel or documentation is in place for this indicator. 2. Initiated: The patient's treatment and follow-up requirements have been identified, responsible experts have been assigned, and development of an individualised plan has begun. 3. Developing: An individualised plan has been drafted, but treatment schedules, monitoring visits, responsibilities, contingency arrangements or patient agreement remains incomplete. 4. Established: A documented individualised plan has been agreed with the patient and defines treatment, monitoring and follow-up schedules, responsible experts, contact pathways, overnight-stay expectations and contingency arrangements.		

Domain 5: Patient partnership and supportive care					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		The patient and caregivers can recognise symptoms requiring urgent review and know how to respond.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Responsibility for providing this education has been assigned to relevant experts.		
			3. Developing: Disease-relevant symptoms have been collated by experts for the patient and family, and the key time points at which this information should be provided have been defined.		
			4. Established: The patient and caregivers have received written and verbal instructions about symptoms, know what actions to take and who to contact, and have demonstrated understanding through an appropriate confirmation method such as teach-back.		
		The patient and caregivers have a direct 24/7 contact pathway to the treating clinical team.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The responsible clinical team has been identified, and arrangements for providing direct contact details are being developed.		
			3. Developing: Contact information has been provided or drafted, but response expectations, handover or escalation arrangements remain incomplete.		
			4. Established: The patient and caregivers have a documented direct 24/7 contact pathway, with confirmed telephone numbers and response expectations clearly set out and understood by the patient and family.		

Domain 5: Patient partnership and supportive care					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		Carer availability and responsibilities are confirmed where required.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The need for a carer has been assessed, expected responsibilities have been discussed and a potential carer has been identified.		
			3. Developing: A carer has been identified, but availability, responsibilities, training, duration of support or backup arrangements remain incomplete.		
			4. Established: Where required, an available carer has been confirmed and appropriately informed or trained, with responsibilities, required availability and backup arrangements documented.		
	Equity and practical support	The patient's accommodation, financial, psychosocial, cultural and language needs are assessed and addressed.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Relevant support needs have been identified, responsibility for completing a needs assessment has been assigned and appropriate support services have been identified.		
			3. Developing: The patient's needs have been assessed and referrals have begun, but accommodation, financial assistance, psychosocial support, cultural support or language services remain incomplete.		
			4. Established: The patient's accommodation, financial, psychosocial, cultural and language needs have been documented, and all required support services and practical arrangements are confirmed before treatment, with input from the patient and family.		

Domain 5: Patient partnership and supportive care					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		Lifestyle factors that may influence treatment delivery or monitoring are assessed and incorporated into planning.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Lifestyle factors that may affect treatment delivery or monitoring have been identified, and discussion with the patient has begun.		
			3. Developing: Relevant lifestyle factors have been assessed, but required modifications, support arrangements or their incorporation into the treatment and monitoring plan remains incomplete.		
			4. Established: Relevant lifestyle factors have been documented and incorporated into the treatment and monitoring plan, with required modifications and support arrangements agreed with the patient.		
		Geographical and logistical requirements for treatment and follow-up are identified, communicated and addressed before treatment.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Travel, accommodation, proximity, transport, caregiving, local healthcare and follow-up requirements have been identified, relevant support services have been contacted, and discussions with the patient have begun.		
			3. Developing: A patient-specific logistical plan is being developed and requirements have been communicated, but transport, accommodation, financial support, local-provider coordination, costs, emergency access or contingency arrangements remain incomplete.		
			4. Established: A documented patient-specific plan addresses travel, accommodation, caregiving, costs, local healthcare, emergency access and follow-up requirements; all arrangements are confirmed before treatment and are understood by the patient.		

Domain 6: Treatment monitoring					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 6	Outcome definition and baseline	A patient-specific clinical trial or treatment protocol is defined.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Responsible experts have been contacted and have confirmed their availability across the implementation period.		
			3. Developing: A patient-specific clinical protocol has been drafted in consultation with the patient and family and reflects agreed treatment goals. However, the dosing rationale, baseline or comparator strategy, clinical outcome assessments, molecular and clinical endpoints, adverse-event definitions and grading, criteria for clinically meaningful change, stopping criteria, analysis plan or follow-up requirements remain incomplete.		
			4. Established: An approved patient-specific clinical protocol, developed with input from relevant experts and the patient and family, defines the therapeutic rationale, trial design, dosing and observation plan, baseline or comparator strategy, clinical outcome assessments, molecular and clinical endpoints, criteria for clinically meaningful change, adverse-event definitions and grading, safety-monitoring requirements, stopping criteria, analysis plan, follow-up schedule and responsible personnel.		
		Patient-relevant outcome measures are selected, and the corresponding efficacy, safety and biological-response endpoints are predefined.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Responsibility has been assigned, and potential outcome measures and endpoints are being identified using natural-history evidence, patient baseline data and patient priorities.		
			3. Developing: Outcome measures and endpoints have been selected, but their justification, assessment methods, time points or criteria for clinically meaningful change (for example, minimal clinically important differences) remain incomplete.		
			4. Established: Evidence-supported outcome measures and endpoints that are meaningful to the patient and clinical team are documented, with assessment methods, time points, required tools and criteria for clinically meaningful change defined.		

Domain 6: Treatment monitoring					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
		Baseline measurements and comparator evidence are documented before treatment.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required baseline assessments and comparator sources have been identified, and data collection has been scheduled.		
			3. Developing: Baseline data have been collected or analysed, but completeness, quality review, comparator selection or multidisciplinary interpretation remains incomplete.		
			4. Established: All required baseline measurements have been completed, quality checked and interpreted by relevant experts, with the comparator strategy documented before treatment.		

Domain 6: Treatment monitoring					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Monitoring plans and pathways	A patient-specific multimodal monitoring schedule is defined.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Required assessments, provisional time points and responsible experts have been identified, and consultation with the patient or family has been scheduled.		
			3. Developing: A draft schedule has been discussed with the patient or family, but assessment time points, responsibilities, sample collection, analytical pathways or logistical arrangements remain incomplete.		
			4. Established: An integrated schedule defines the relevant molecular, biochemical, haematological, immunological, pharmacokinetic, neurophysiological, radiological, developmental, functional and patient-reported assessments. Peri-treatment and long-term time points, responsible experts, tools, sample collection and analytical pathways are confirmed and aligned with the predefined endpoints.		
		Therapy- and organ-specific toxicity-monitoring and escalation pathways are established.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Known and plausible toxicities (for example, hepatic or immune toxicity), their anticipated severity and timing, the required assessments, responsible experts and relevant specialist or rescue services have been identified.		
			3. Developing: Monitoring pathways have been drafted, but schedules, responsibilities, intervention thresholds, specialist access or escalation arrangements remain incomplete.		
			4. Established: Operational pathways define toxicity assessments, time points, responsible experts, intervention thresholds and escalation to relevant specialist or rescue services throughout treatment and follow-up.		

Domain 6: Treatment monitoring					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Multidisciplinary review and treatment decisions	A multidisciplinary oversight process reviews monitoring results and guides treatment decisions.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The required experts, review intervals and treatment-decision criteria have been identified.		
			3. Developing: Relevant experts have been engaged, but review schedules, responsibilities, integration of monitoring results or decision criteria remain incomplete.		
			4. Established: A multidisciplinary committee reviews safety and efficacy data according to predefined peri-dose and post-dose schedules and following major safety events. Clinical findings and investigation results are evaluated against baseline, natural history and the predefined endpoints, with decisions to continue, repeat, modify, pause or stop treatment documented.		
	Pharmacovigilance	Definitions and procedures for pharmacovigilance and adverse-event reporting are established.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Adverse-event definitions (including serious and non-serious events), grading and attribution methods, reporting requirements, timelines, recipients and responsible experts have been identified.		
			3. Developing: Procedures have been drafted, but documentation tools, reporting pathways, responsibilities or follow-up requirements remain incomplete.		
			4. Established: Approved procedures define how potential adverse events are identified, graded, attributed, documented, reported and followed up, with timelines, recipients, reporting systems and responsibilities specified.		

Domain 7: Evidence governance and collaborative learning					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
Domain 7	Data management and quality assurance	Data-management and quality-assurance processes ensure that longitudinal data are complete, accurate, secure and traceable.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: The data to be captured, responsible experts, storage locations and applicable data-governance and privacy requirements have been identified, and development of data-management arrangements has begun.		
			3. Developing: Data-management procedures are drafted or partly implemented, but source-data verification, access control, security, back-up, audit trails or quality review remains incomplete.		
			4. Established: Approved processes define data capture, source-data verification, coding, access control, security, back-up, audit trails, retention and periodic quality review, with responsibilities assigned and longitudinal data demonstrably complete, accurate, secure and traceable.		
		Patient data and biological samples are registered and retained so that outcomes can be evaluated over the long term.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Applicable registries, biobanking arrangements, consent requirements and responsible experts have been identified.		
			3. Developing: Registry enrolment or sample banking has begun, but consent scope, data fields, submission schedules, sample tracking or retention arrangements remain incomplete.		
			4. Established: The patient is enrolled in an appropriate registry and samples are banked under applicable consent, with defined data fields, submission schedules, sample tracking and retention periods documented.		

Domain 7: Evidence governance and collaborative learning					
Domain	Subdomain	Indicator	Maturity levels	Maturity level assessment	Rationale and evidence
	Collaborative learning networks	The team participates in relevant collaborative learning networks and contributes protocols, outcome data and biological samples where appropriate and permitted.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Relevant networks, responsible experts, shareable materials and the applicable consent and governance requirements have been identified, and process development has begun.		
			3. Developing: Sharing agreements or procedures have been drafted or partly implemented, but permissions, de-identification, secure transfer, sample handling, record keeping, network participation or feedback procedures remain incomplete.		
			4. Established: An approved process defines network engagement, responsible representatives, consent and governance checks, secure transfer and handling, complete records of what has been shared, and incorporation of feedback.		
		Clinical protocols are reviewed and updated using emerging evidence and treatment experience.	1. Not established: No capability, process, personnel or documentation is in place for this indicator.		
			2. Initiated: Responsible experts, evidence sources, review intervals and triggers for protocol review have been identified, and process development has begun.		
			3. Developing: Protocol reviews occur, but evidence appraisal, decision-making, approval, communication or implementation of revisions remains incomplete.		
			4. Established: An approved process defines scheduled and trigger-based evidence review, appraisal, decision-making, change control, approval, version control, communication and implementation of protocol revisions.		