

Decompressive Craniectomy After Aneurysmal Subarachnoid Hemorrhage: An International Multicenter Retrospective Patient-Level Cohort Study

DECIDE-SAH - DEcompressive Craniectomy In SAH: an International Data-Driven Evaluation

Protocol | Version 2.4 | 14 October 2026

Study design	International, multicenter, retrospective, observational, non-interventional secondary-use patient-level cohort study using pre-existing routine-care data
Retrospective data cut-off	15.09.2026
Planned project period	2026 to 31.12.2031
Study registration	ClinicalTrials.gov — NCT07872774
Essen ethics opinion	Favorable opinion for the initial Essen submission, Ethics Committee of the University of Duisburg-Essen | 13 October 2026 | 26-13319-BO
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Coordinating center	Department of Neurosurgery and Spine Surgery, University Hospital Essen, Germany
Coordinating Investigator	Prof. Dr. med. Ramazan Jabbarli
Co-Investigator	Prof. Dr. med. Ulrich Sure
Study Coordinator	Prof. Dr. med. Marvin Darkwah Oppong
Statistical Lead	Prof. Dr. Börge Schmidt, Institute for Medical Informatics, Biometry and Epidemiology (IMIBE), University Hospital Essen

1. Protocol synopsis

Item	Description
Primary objective	To evaluate the association between decompressive craniectomy (DC) strategies and unfavorable functional outcome at approximately 6 months after aneurysmal subarachnoid hemorrhage (aSAH), with particular emphasis on treatment timing, neurological status at the treatment decision, indication and technical characteristics.
Primary endpoint	Modified Rankin Scale (mRS) 4-6 at approximately 6 months. Routine-care assessments obtained within 3-9 months are eligible; the assessment closest to day 180 is used.
Population	Adults aged >=18 years with eligible aSAH due to rupture of a qualifying intracranial aneurysm, managed at participating neurovascular/neurosurgical centers. Eligible aneurysm morphologies include saccular, blister-like, dissecting, fusiform and other non-excluded aneurysmal morphologies; infectious/mycotic aneurysms, traumatic or iatrogenic pseudoaneurysms, and AVM-/AVF-associated flow-related aneurysms are excluded. Each center contributes the largest reliably available consecutive retrospective cohort within its approved data period.
Cohort size	Availability-based design without a fixed recruitment target. Essen comprises approximately 2,500 aSAH patients treated since approximately 1980; the number contributed by future external centers is not reliably estimable before site activation and source-data mapping.
Data architecture	Minimum Required Dataset (MRD) -> Standard Dataset -> optional Extension Modules.
Exposure framework	Exact or best-available ictus-to-DC timing, treatment-decision severity, indication and technical characteristics are prioritized. Source Primary/Secondary DC classification is retained as a pragmatic variable. Any-DC versus no-DC comparisons are descriptive; the SAP will prespecify clinically comparable treatment-strategy comparisons supported by the available temporal granularity.
Statistics	Multilevel models with center effects where feasible; propensity/risk-set adjustment; treatment-era adjustment; timing-aware landmark/risk-set/target-trial-emulation-oriented analyses when data permit; prespecified missing-data and sensitivity analyses.
Data protection	No direct identifiers. Pseudonymized working data only where lawfully authorized; otherwise anonymous site export. A documented anonymization lock is performed before final central statistical analysis.
Site activation	University Hospital Essen is the coordinating center at study initiation. Additional centers may join after local regulatory requirements are completed and are added through the applicable amendment process before patient-level transfer.

Item	Description
Future optional substudies	Imaging/DICOM/computer-vision/AI and cranioplasty-related follow-up may be studied as separately governed optional substudies; they are not part of the main study dataset.

2. Administrative structure and governance

2.1 Coordinating center and leadership

The Department of Neurosurgery and Spine Surgery, University Hospital Essen, Germany, serves as coordinating center. Prof. Dr. med. Ramazan Jabbarli is the Coordinating Investigator and is responsible for scientific leadership, protocol governance, site activation, oversight of data harmonization and primary reporting. Prof. Dr. med. Ulrich Sure serves as Co-Investigator, Prof. Dr. med. Marvin Darkwah Oppong as Study Coordinator, and Prof. Dr. Börge Schmidt (IMIBE) as Statistical Lead.

2.2 Participating centers

DECIDE-SAH is designed as an international multicenter study. A center becomes a participating site after a locally responsible investigator has been designated, the applicable local ethics/data-protection basis has been documented, the common protocol and data specification have been accepted, and the required institutional arrangements for local data processing and any proposed data transfer have been completed. Expressions of interest, aggregate feasibility submissions and survey responses do not constitute site activation or authorization to transfer patient-level data. Where several hospitals contribute through a regional network or shared registry, the originating institutions, responsible local investigators, cohort periods and any overlap between patient populations must be documented before inclusion. Additional centers are incorporated through the applicable ethics/amendment or notification process before their patient-level data transfer begins.

2.3 Governance bodies

- Executive Committee: protocol governance, data-quality thresholds, approval of the statistical analysis plan (SAP), publication governance and substudy approval.
- Statistical Analysis and Data Harmonization Group: IMIBE-led harmonization, missing-data strategy, center/era effects, causal-inference-supportive analyses and final statistical reporting.
- International Steering Committee: scientific advisory representation of participating centers and relevant methodological experts as the network develops.

3. Background and rationale

Aneurysmal subarachnoid hemorrhage is a severe neurovascular emergency associated with substantial mortality and long-term disability. Brain edema, intracerebral hemorrhage, hydrocephalus, early infarction, delayed cerebral ischemia and intracranial hypertension may result in life-threatening mass effect and secondary injury. Decompressive craniectomy is used in selected patients, but the available evidence is predominantly observational and heterogeneous, with strong confounding by indication and marked variation in timing, indication and technical extent.

Previous work from the Essen group and collaborators indicates that intracranial-pressure burden, early cerebral infarction, early brain edema, the timing and extent of decompression and baseline risk profiles may influence patient selection and outcome. DECIDE-SAH therefore evaluates DC as a timing-, indication-, severity- and technique-dependent treatment strategy rather than as a simple binary exposure. A large international patient-level dataset can characterize practice heterogeneity and support more rigorous observational analyses while acknowledging residual confounding.

4. Objectives

4.1 Primary objective

To evaluate the association between decompressive craniectomy and unfavorable functional outcome at approximately 6 months after aSAH, defined as mRS 4-6, with particular emphasis on DC timing, baseline/decision-time neurological status, indication and technical characteristics.

4.2 Key exploratory objectives

- Characterize outcome associations across exact or best-available ictus-to-DC timing and pragmatic Primary/Secondary DC classifications.
- Identify clinically plausible subgroups in which early or pre-emptive decompression is associated with different outcomes than delayed or rescue decompression.
- Assess the contribution of hemorrhage burden, ICH, IVH, hydrocephalus, cerebral edema, infarction and ICP burden to treatment selection and outcome.
- Evaluate technical characteristics of DC, including type, extent/surface where available, duraplasty, concomitant ICH evacuation, complications and revision surgery.
- Describe center-level variation in DC practice, neurocritical-care structure, DCI/vasospasm management and treatment era.

4.3 Optional future substudy domains

Optional future substudies may address imaging/DICOM/computer-vision/AI analyses and cranioplasty-related follow-up, including timing, implant/material and procedure-related complications. These domains require dedicated data specifications and any additional governance or transfer approvals applicable at the time.

5. Study design and time framework

DECIDE-SAH is an international, multicenter, retrospective, observational and non-interventional secondary-use study using patient-level information generated during routine clinical care. There is no randomization, prospective treatment allocation, study-specific diagnostic or therapeutic procedure, investigational product or study-related patient contact. Clinical management was determined independently by the treating teams.

5.1 Retrospective data cut-off

Only routine-care information documented on or before 15.09.2026 is eligible for the study dataset under this protocol. A center may contribute its largest reliably available consecutive historical aSAH cohort within this data-availability framework. Any future extension of the retrospective data cut-off requires a protocol amendment and all applicable approvals; no study-specific prospective follow-up is generated.

5.2 Project period and operational phases

Phase	Indicative period	Main activities
Central setup	2026	Ethics/governance, ClinicalTrials.gov registration, AIDG/UAC, master data specification and study materials.
Site activation	2026-2028	Formal addition of external sites, local approvals/waivers, transfer agreements and data mapping.
Retrospective extraction and QC	2027-2029	Local retrospective extraction, approved transfer, central range/timing/missingness checks and structured queries.
Harmonization / extensions / SAP	2028-2030	Cross-center harmonization, analysis definitions, optional extensions and final SAP before database lock.
Database lock / analysis / dissemination	2030-2031	Anonymization lock, database lock, primary/secondary analyses and dissemination.

These periods are operational planning windows rather than patient accrual periods and may overlap. The planned project end is 31.12.2031 unless the primary project is completed earlier.

6. Study population and cohort scope

6.1 Inclusion criteria

- Age >=18 years at ictus/admission.

- Aneurysmal subarachnoid hemorrhage due to rupture of a qualifying intracranial aneurysm. Eligible aneurysm morphologies include saccular, blister-like, dissecting, fusiform and other non-excluded aneurysmal morphologies.
- Management at a participating center during its documented consecutive retrospective cohort period.
- Minimum Required Dataset can be satisfied for scientific cohort contribution.

6.2 Exclusion criteria

- Non-aneurysmal subarachnoid hemorrhage, including SAH caused primarily by another vascular lesion without a qualifying ruptured intracranial aneurysm, and traumatic subarachnoid hemorrhage.
- Rupture of an infectious/mycotic aneurysm, traumatic pseudoaneurysm, iatrogenic pseudoaneurysm, or an AVM-/AVF-associated flow-related aneurysm.
- Insufficient information to establish the aSAH diagnosis or MRD entry threshold.

6.3 Consecutive cohort principle and treatment limitation

Centers should contribute consecutive eligible aSAH cases rather than selected DC cases. The denominator comprises eligible patients with and without DC. Having no eligible DC procedures during the documented cohort period does not, by itself, preclude center participation. Case ascertainment must be traceable to the local source population; overlapping contributions from shared registries, referrals or interhospital transfers should be identified and resolved without disclosure of direct identifiers. Patients with treatment limitation are not excluded a priori from the descriptive cohort because such exclusion may introduce selection bias. Treatment limitation and its timing are documented when available and handled through prespecified analysis restrictions and sensitivity analyses.

6.4 Cohort size and sample-size rationale

DECIDE-SAH is an availability-based retrospective cohort and therefore does not use a fixed recruitment target derived from a prospective power calculation. The Essen source population comprises approximately 2,500 patients with aSAH treated since approximately 1980. The number of patients contributed by future external centers cannot be estimated reliably before site activation and source-data mapping. Each center will therefore contribute the largest reliably available consecutive cohort within the approved retrospective period. Analysis-specific model complexity and subgroup analyses will be restricted to datasets with sufficient outcome events, covariate completeness and statistical stability; detailed rules will be prespecified in the SAP.

7. Data architecture and participation threshold

The data model is hierarchical. The MRD is the minimum information required for scientifically interpretable cohort contribution. The Standard Dataset contains the regular patient-level variables and should be completed as fully as reliable source data permit. Extension Modules provide optional granular data and may be supplied together with the Standard Dataset or at a later approved stage. EXT_ICP is not restricted to decompressed patients: it may be completed for patients with or without DC when the ICP course and ICP-directed treatment are reliably reconstructable.

MRD component	Minimum requirement
Patient identifier	Technical center-prefixed record ID; no direct identifiers.
Admission timing	At least MM.YYYY; exact date/time preferred when reliably available and permitted.
Age	Age in years.
Sex	Documented sex category.
Initial clinical severity	Good Grade or Poor Grade with center/source definition; exact WFNS/HH/GCS preferred.
Aneurysm treatment	Treatment status and modality known; None if untreated.
DC status	No DC / Primary DC / Secondary DC; source classification required if DC occurred.
Discharge outcome	At least one interpretable discharge clinical outcome; mRS preferred.

8. Exposure definition: decompressive craniectomy

8.1 Hierarchical exposure concept

The principal exposure is decompressive craniectomy during the index hospitalization. Exact timing and treatment-decision context are prioritized when available. The center/source Primary versus Secondary DC label is retained as a pragmatic variable because retrospective documentation and local terminology may differ across centers. Primary versus Secondary DC is not defined by a fixed ictus-to-DC hour threshold. Exact dc_time, aneurysm-treatment timing and indication components permit central timing- and risk-set-based analyses that are not dependent on the local label alone.

8.2 Standard DC variables

- dc_any; dc_primary_secondary; dc_time; dc_type; redo_dc and redo_dc_datetime.
- midline_shift_pre_dc_mm based on imaging immediately preceding the first recorded DC when reconstructable.
- Independent indication components: ICH, diffuse cerebral edema/swelling, refractory ICP elevation, cerebral infarction with edema and other documented indication with free-text clarification.
- For Secondary DC: gcs_pre_sdc and herniation/anisocoria immediately before the first Secondary DC when available.

8.3 Technical extension

EXT_DC uses one row per DC event and records event class/time, type/configuration, craniectomy dimensions or surface area when available, surface measurement method, duraplasty, ICH evacuation, additional brain resection, operative details, complications and revision surgery.

9. Other clinical domains

9.1 Initial severity / pretreatment

Admission WFNS, Hunt-Hess/Hunt-Kosnik and GCS are preferred Standard variables. The MRD accepts a documented Good Grade/Poor Grade classification when exact scores are unavailable. Admission herniation/anisocoria and aneurysmal rebleeding before definitive aneurysm treatment are captured separately.

9.2 Imaging and aneurysm

Standard variables include Fisher/modified Fisher grade, IVH, ICH, ICH volume when available, SEBES, acute hydrocephalus/treatment, aneurysm location, aneurysm morphology and size. EXT_RADIOLOGY supports additional source-documented scores and a local DICOM-availability flag.

9.3 Aneurysm and acute treatment

Aneurysm treatment status/modality is MRD. Treatment timing, nimodipine route and post-treatment antithrombotic treatment are Standard variables when available.

9.4 ICP, vasospasm, DCI and infarction

ICP monitoring method, initial ICP >20 mmHg when invasive ICP data are available, therapy-requiring ICP elevation and total ICP-treatment days are collected when reliably reconstructable. therapy_requiring_icp_elevation and icp_treatment_days are cohort-wide summary measures and are not restricted to patients undergoing DC. EXT_ICP may be completed in patients with or without DC and records the first and last documented therapy-requiring ICP episode, a controlled multi-select description of ICP-directed treatment components (including active CSF drainage, deep sedation/analgesia, osmotherapy, neuromuscular blockade, controlled hyperventilation/PaCO2 reduction, temperature management/hypothermia, barbiturate therapy, CPP-targeted hemodynamic support and other documented conservative ICP-directed treatment), and optional temporal detail. Pre-/post-DC ICP timing fields are supplementary and apply only when DC occurred. DC itself is captured in the dedicated DC variables and is not duplicated as an ICP-treatment component. TCD vasospasm, angiographic vasospasm, clinical DCI, early cerebral infarction and DCI-associated infarction are retained as distinct concepts. DCI definitions follow the Vergouwen consensus where applicable.

9.5 Systemic complications and hydrocephalus

The Standard Dataset captures core infectious/ICU outcomes. EXT_SYSTEMIC_COMPLICATIONS records detailed infectious, respiratory, cardiovascular, thromboembolic, renal and multiorgan events. EXT_CHRONIC_HYDROCEPHALUS records VPS timing, revision and available source-documented shunt/hydrocephalus scores.

10. Outcomes

10.1 Primary endpoint

Unfavorable functional outcome at approximately 6 months, defined as mRS 4-6. Routine-care assessments within 3-9 months are eligible. When more than one assessment is available, the assessment closest to day 180 is selected; when two are equally close, the later assessment is used. The primary analysis includes only outcomes already documented within the applicable retrospective data-availability framework.

10.2 Secondary endpoints

- Ordinal mRS and alternative mRS dichotomizations; discharge outcome; in-hospital and later mortality where documented.
- mRS at approximately 12 and 24 months when retrospectively available within the approved data window.
- GOS/GOSE-based harmonized outcomes where mRS is unavailable.
- ICU/hospital length of stay, infarction/DCI, ICP burden, hydrocephalus/VPS, systemic complications and DC-related complications.

10.3 Cohort eligibility versus analysis eligibility

MRD eligibility is intentionally broader than eligibility for the primary 6-month analysis. A center or patient record may contribute valid descriptive or secondary analyses even when 6-month mRS is unavailable. Analysis-specific populations will therefore be prespecified and missingness will be reported by variable and center.

11. Data sources, retrospective extraction and center-level context

The uniform patient-level scientific data source is pre-existing information generated during routine clinical care. Local technical systems may include electronic health records, ICU documentation, operative reports, radiology reports/PACS, discharge letters, follow-up documentation and local clinical databases used as case-finding or extraction aids. Different local storage systems do not constitute different patient-level study protocols, and participation does not require a pre-existing registry. A separate, voluntary center-level ICP/DC practice survey may collect aggregate institutional descriptions and estimated practice patterns from designated clinical representatives (normally one coordinated response per center). This survey is not a source of additional patient-level records, does not retrospectively alter clinical management, and is not a requirement for cohort participation or site activation. Any linkage of survey information with patient-level cohort analyses must be covered by the applicable institutional and ethics/data-governance approvals and the prespecified analysis plan.

12. Data management, privacy and data flow

12.1 Local extraction and identifiers

Direct identifiers remain at the contributing institution. Each site uses a technical record identifier across the DECIDE-SAH data sheets; any mapping to the local clinical record remains under local control. Where a pseudonymized transfer is legally authorized, such keys are not provided to the coordinating center. For a proposed anonymous site export, the originating and receiving institutions must assess whether identification remains reasonably possible in context; substituting a technical record ID alone does not establish anonymity. Names, full date of birth, postal addresses, insurance identifiers, hospital record numbers, local re-identification keys and directly identifying documents are not accepted centrally.

12.2 Site-specific lawful transfer

The common scientific protocol does not presume one identical legal mechanism for all countries or institutions. Before extracting data for research, each site documents the lawful basis and any required ethics, professional-secrecy and institutional permission

for retrospective local secondary use. Before exporting or transferring any patient-level data, the sending and receiving institutions separately document the permitted data form, applicable cross-border requirements, contractual arrangements, safeguards and approved technical route. Pseudonymized patient-level data may be transferred only where lawfully and institutionally authorized; where this is not authorized, only an export assessed and approved as sufficiently anonymous may be considered. If neither route is authorized, no central patient-level data transfer occurs. The scientific site-activation decision is not a substitute for these approvals.

12.3 Central working dataset and query resolution

The coordinating center performs range, missingness, timing-sequence, duplicate and cross-domain plausibility checks. Queries are returned to sites using the approved record identifier or local query process. No attempt at re-identification by the coordinating center is permitted. The working dataset is stored in an institutionally approved environment and is accessible only to authorized study personnel under role-based access controls.

12.4 Anonymization lock before final analysis

After the planned query-resolution phase, a documented anonymization assessment and, where the applicable standard can be met, an anonymization lock are performed before release of the final central analysis dataset. Working identifiers are removed or irreversibly replaced, center identifiers are recoded for analysis, unnecessary absolute calendar dates are removed or transformed after derivation of analytically required intervals and treatment-era variables, rare categories or unusually identifying combinations are generalized or suppressed where necessary, and small-cell/disclosure risk is reviewed. The final dataset may be designated and released as anonymous only after the applicable institutional data-governance review confirms that the risk of identification has been reduced sufficiently in the intended use context. If that assessment is not satisfied, the dataset remains subject to the approved restricted-data controls and cannot be described or released as anonymous; final central statistical analysis on such a dataset would require a separate protocol amendment and applicable approvals.

12.5 International transfer and future imaging

External sites are responsible for local ethics/IRB, data-protection, contractual and international-transfer requirements. Data may be transferred only through an institutionally approved route. Imaging/DICOM transfer is not part of the main study dataset and requires separate governance.

13. Ethics and regulatory framework

DECIDE-SAH is retrospective secondary-use research using pre-existing routine-care patient data and involves no study-specific intervention, patient contact or prospective patient recruitment. The Ethics Committee of the University of Duisburg-Essen issued a favorable opinion on 13 October 2026 (reference 26-13319-BO) for the initial Essen submission. Protocol changes and additions of participating sites follow the applicable ethics, amendment or notification procedures. Each participating center must complete any required local ethics-committee notification/review (including provision of the coordinating-center decision where applicable), as well as its own statutory, confidentiality, data-protection and institutional conditions, before initiating locally regulated study activities and before any patient-level data transfer. Approval for secondary use, authorization for export and approval for central receipt are documented separately. The voluntary, aggregate center-level practice survey, if implemented or used for scientific analysis, is likewise subject to any applicable approvals. DECIDE-SAH is registered with ClinicalTrials.gov under the identifier NCT07872774 (registration confirmed on 13 October 2026). The registry record is maintained and updated as required.

14. Statistical analysis framework

14.1 General principles

Analyses are observational. The statistical framework is intended to reduce, not eliminate, confounding by indication, treatment-selection bias, center effects, treatment-era effects and timing/immortal-time bias. Treatment-effect language will be calibrated to observational evidence.

14.2 Main analysis strategy

- Primary binary endpoint: mRS 4-6 at approximately 6 months.
- Multilevel outcome modeling with center effects where feasible.
- Propensity-score weighting/matching or related adjustment using pre-exposure variables.
- Calendar/treatment-era adjustment and center-level covariates when data support stable estimation.
- Timing-aware landmark, risk-set and target-trial-emulation-oriented analyses when temporal resolution and confounder information are sufficient; otherwise analyses are explicitly labeled descriptive/exploratory.
- The SAP will prespecify the principal clinically comparable DC strategy comparisons supported by the available data; a single crude any-DC versus no-DC contrast will not be treated as sufficient for causal interpretation.

14.3 Missing data and heterogeneity

Missingness will be summarized by variable and center. Complete-case analyses, multiple imputation and sensitivity analyses restricted to centers with high completeness may be used according to the final prespecified SAP. No variable with prohibitively high missingness will be treated as universally mandatory unless required for a specific analysis.

14.4 Sample-size considerations

The study is based on the available consecutive cohorts rather than a fixed prospective recruitment target. The Essen cohort contains approximately 2,500 aSAH patients treated since approximately 1980. The aggregate international sample size will depend on the number and size of participating centers. Effective sample size, number of outcome events and covariate completeness will determine the permitted complexity of multivariable, propensity-based and subgroup analyses; unstable models or inadequately supported subgroup analyses will not be interpreted as confirmatory.

15. Quality control

- Standardized workbook, data dictionary and SOP.
- Documented MRD entry threshold and center-level source definitions.
- Central range, timing, sequence, consistency and duplicate checks.
- Center-specific missingness and structured query reports.
- No inference of unavailable values from clinical probability alone.
- Database lock only after planned query resolution and the documented anonymization lock.

16. Optional imaging/AI and cranioplasty substudies

Imaging/DICOM/computer-vision/AI analyses and cranioplasty-related follow-up are optional future substudies. Any such substudy requires a dedicated data specification, participating-site opt-in and any additional ethics/data-transfer approvals required at that time.

17. Authorship and publication policy

Authorship and publication follow ICMJE criteria and the separately controlled DECIDE-SAH publication governance. Data contribution alone does not automatically confer individual named authorship. Manuscript-specific authorship decisions consider substantive scientific and manuscript contributions together with the size, reliability, completeness and granularity of the contributed cohort, without predetermined quotas or guaranteed positions. The study may acknowledge additional eligible contributors as group members or collaborators under the applicable journal and indexing rules; collaborator listing does not itself guarantee individual author indexing. Substudies and analyses of pooled data require Executive Committee approval; centers retain the right to analyze their own local data independently provided unpublished pooled DECIDE-SAH results are not disclosed.

18. Funding and support

DECIDE-SAH is investigator-initiated and non-commercial. No routine per-patient reimbursement or site-initiation fee is planned. Central coordination, data management and statistical infrastructure are initially supported by institutional/departmental resources. External academic funding may be sought for central infrastructure without changing the scientific independence of the project.

19. Protocol amendments

Substantial changes affecting the study population, retrospective data cut-off, endpoints, patient-level data specification, ethics/data-transfer framework or participating sites will be submitted to the coordinating Ethics Committee and other responsible bodies as required before implementation. Addition of further sites will follow the mechanism accepted by the coordinating committee, which may include consolidated site-list submissions where expressly permitted; no automatic blanket authorization is presumed. Controlled SOP, dictionary and workbook revisions must remain aligned with the approved scientific scope and be versioned and assessed for their impact on ethical or institutional approvals.

20. End of study and data retention

The planned project period ends on 31.12.2031 or earlier after completion of the primary analysis and reporting, depending on operational progress. Pseudonymized working data will not be retained longer than scientifically and legally necessary. After completion of QC and query resolution, the central working dataset is released for final central analysis only upon documented and institutionally approved anonymization; if this cannot be achieved, the dataset remains restricted and an amended protocol and applicable approvals are required before any alternative final analysis pathway. Project documentation is retained according to applicable institutional requirements.

21. Core references

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