International Site Starter Guide

Scientific feasibility, data architecture and activation pathway - DECIDE-SAH

Document version / date	v1.2 / 14 October 2026
Scientific basis	Scientific Protocol v2.4 (14 October 2026)
Operational data set	Workbook + SOP + eCRF Data Dictionary v2.3

Purpose. This guide helps centers evaluate existing retrospective aSAH cohorts and the DECIDE-SAH participation pathway. Patient-level extraction and transfer require the applicable ethics, institutional, contractual and data-protection authorizations.

1. What DECIDE-SAH is

DECIDE-SAH is an international multicenter retrospective, observational, non-interventional secondary-use study of adult aneurysmal subarachnoid hemorrhage. It evaluates decompressive craniectomy as a timing-, indication-, severity- and technique-dependent treatment strategy rather than as a simple DC-versus-no-DC exposure. The current protocol uses routine-care information already documented on or before 15.09.2026.

2. How a center enters the collaboration

Stage	What the center does	What it means
1. Interest	Review the study overview and discuss local fit.	No commitment; no data transfer.
2. Participation Intent	Return the one-page Participation Intent Confirmation.	Confirms willingness to participate, subject to local requirements; no feasibility data.
3. Feasibility	Complete the Center Feasibility & Cohort Profile Form.	Aggregate review of cohort size, source systems, variable availability and local practice.
4. Regulatory activation	Complete applicable ethics/privacy/contractual/technical steps.	Only after mandatory gates are complete can a patient-level contribution pathway be activated.
5. Data contribution	Map the local cohort to the controlled DECIDE-SAH specification and approved pathway.	Dataset enters QC/query workflow.

3. What to review first

- Scientific Protocol v2.4 (14 October 2026)
- External Site Data Collection Workbook v2.3.
- Data Collection SOP v2.3.
- eCRF Data Dictionary / Variable Architecture supplied with the same operational release.
- This Site Starter Guide and the Data Protection & International Data Flow Concept.

The controlled Workbook, SOP and Data Dictionary define the variables. This guide summarizes them but does not override them.

4. Three-level data architecture

Level	Purpose	Participation rule
Minimum Required Dataset (MRD)	Scientific entry threshold for an interpretable consecutive aSAH cohort.	Required for cohort contribution; not a complete-case requirement.
Standard Dataset	Main patient-level dataset from baseline through outcome.	Complete as fully as reliable source data permit; individual Standard missingness does not automatically exclude a center.
Extension Modules	Optional granular modules for radiology, ICP, infarction, DC, systemic complications and chronic hydrocephalus.	Optional; may be supplied with Standard data or at a later approved stage.

5. Minimum Required Dataset

MRD component	Controlled field(s)	Minimum acceptable information
Patient identifier	study_id	Center-prefixed technical record ID; no direct identifiers.
Admission timing	admission_time	At least month/year; higher reliable precision preferred.
Age	age	Age in years.
Sex	sex	Documented sex category.
Initial clinical severity	clinical_severity_binary + clinical_severity_source	Good Grade / Poor Grade plus source definition; exact WFNS/HH/GCS preferred.
Aneurysm treatment	aneurysm_treatment	Known treatment status/modality; use None if untreated.
DC status	dc_any + dc_primary_secondary if DC performed	No DC / Primary DC / Secondary DC; exact timing is separate Standard information.
Discharge outcome	mrs_discharge or approved discharge alternative	At least one interpretable discharge outcome; mRS preferred.

6. High-priority mapping rules

Topic	Controlled rule
Cohort ascertainment	Consecutive case ascertainment is the standard. A non-consecutive source must be declared and requires central scientific review.
Existing registry	A formal pre-existing registry is not required; reliable retrospective case finding from EHR/ICU/operative/radiology/local database sources may be acceptable.
Aneurysm eligibility	Eligible culprit 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.
Aneurysm morphology	Record aneurysm_morphology in the Standard Dataset.
Ictus timing	ictus_time is Standard, not MRD. Use the highest reliable precision; do not invent an exact time/date.
Admission herniation	Use herniation_anisocoria_admission. Do not create parallel pupil/herniation variables.
Primary DC	Do not duplicate a generic pre-DC status; baseline/admission status is the relevant clinical context.
Secondary DC	Use gcs_pre_sdc and herniation_anisocoria_pre_sdc immediately before the first Secondary DC where available.
DC classification	Primary/Secondary is the local/source classification. Exact dc_time is recorded separately; classification is not defined by a fixed ictus-to-DC hour threshold.
DC indication	Use ICH/mass effect, diffuse cerebral edema/swelling, refractory ICP elevation, cerebral infarction with edema, or other documented indication. Hydrocephalus and vasospasm are not separate immediate DC-indication categories.
GOS/GOSE	Use existing gos/gose plus assessment datetime. They satisfy the MRD discharge-outcome component only when the recorded assessment represents hospital discharge.
DICOM	Document local DICOM availability only. Main-study central DICOM transfer is not included.
ICP course	therapy_requiring_icp_elevation and icp_treatment_days apply to DC and non-DC patients when reliably reconstructable; invasive monitoring is not required for these two summary variables.

7. Optional Extension Modules

Module	Scope
EXT_RADIOLOGY	Additional source-documented radiographic scores and local DICOM-availability flag.
EXT_ICP	Applicable with or without DC: first/last therapy-requiring ICP episode plus controlled multi-select treatment components; pre-/post-DC duration fields only if DC occurred.
EXT_INFARCTION	Up to three newly documented infarct events with timing, modality and location.
EXT_DC	One row per DC event: event number/class/time, technical details, dimensions/surface, duraplasty, ICH evacuation, complications and revision.
EXT_SYSTEMIC_COMPLICATIONS	Detailed infectious, respiratory, cardiovascular, thromboembolic, renal and multiorgan complications.
EXT_CHRONIC_HYDROCEPHALUS	VPS timing/revision and source-documented shunt/hydrocephalus scores.

8. Data protection and transfer in brief

- No direct identifiers or local linkage keys are accepted centrally.
- Pseudonymized patient-level transfer is used only where lawfully/institutionally authorized; otherwise an anonymous site export may be used where approved.
- Participation Intent and Feasibility do not authorize patient-level transfer.
- No cross-border transfer begins until the applicable ethics/privacy/contractual/technical pathway is complete.
- Central DICOM/image transfer is outside the main study.
- Any exceptional alternative analysis pathway requires separate governance approval.

9. What not to do

- Do not select only DC cases or only patients with complete outcomes when defining the source cohort.
- Do not infer undocumented values from clinical probability.
- Do not create local replacements for controlled variable definitions without central discussion.
- Do not send patient-level data before formal activation.
- Do not send direct identifiers, linkage keys or raw DICOM imaging as part of the main-study dataset.

10. Scientific coordination

Prof. Dr. med. Ramazan Jabbarli
Coordinating Investigator
Department of Neurosurgery and Spine Surgery | University Hospital Essen, Germany
ramazan.jabbarli@uk-essen.de | info@decide-sah.com | https://decide-sah.com
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