

# Giant Intracranial Aneurysm Registry

## Manual

All patients aged 18 and older with an intracranial giant aneurysm (minimum diameter: 25 mm) are documented using the **Basic Module** data sheet and the **Follow-Up** data sheets (1, 3 and 5 years after inclusion). The following paragraphs assist in filling out these data sheets. Please note that data inclusion can be done either using the fax-forms or by access to the web-based data bank. In case of questions please feel free to contact the register's coordinating office (phone: ++49 – 30 – 450 660 069 / email: julius.dengler@charite.de).

**At first, here is a brief overview of the giant aneurysm registry:**

### Giant Aneurysm Registry

#### Prospective Arm in 5 Steps

(for patients you have not treated earlier)

##### 1 – Inclusion Criterion:

There is only 1: the diagnosis of an intracranial aneurysm with a diameter of at least 25 mm. Thrombus and wall structures also count as part of the aneurysm, so please use both MRI (with TOF) and 3D- (or regular) Digital-Subtraction-Angiography for diameter measurement and diagnosis.

##### 2 – Prospective Inclusion:

Patients that you have not treated before and now present to you for treatment go into the prospective arm. Please read the patient information form to the patient (or legal representative) and ask to sign the consent form.

##### 3 – Create a pseudonym (=patient ID):

Character	1	2	3	4	5	6	7	8
	2 <sup>nd</sup> letter of first name	2 <sup>nd</sup> letter of last name	"100" minus last 2 digits of year of birth		your registry center number			the number the patient has on your list of inclusion

**EXAMPLE:** Paul Miller, born in 1951, is the 22<sup>nd</sup> patient the registry center in Munich (center number "16") includes prospectively. He receives the ID: a i 4 9 1 6 2 2.

##### 4 – Basic Module:

Please fill in the "Basic Module" data sheet. If an endovascular or surgical therapy is chosen, please use the time period in which the patient is accepted to the ward for therapeutic intervention for the Basic Module. For patients you wish to treat conservatively please use the initial contact with the patient for the Basic Module.

##### 5 – Follow-Up:

Please conduct 3 follow-up examinations (1 year, 3 years and 5 years after inclusion) and fill in the Follow-Up data sheets. A time frame of ± 3 months at each examination is acceptable. We encourage you to take part in the imaging projects of the Registry, for which we ask you to conduct an MRI (with TOF) and a 3D- (or regular) Digital-Subtraction-Angiography at each follow up examination.

### Giant Aneurysm Registry

#### Retrospective Arm in 5 Steps

(for patients that were treated by you in the past - starting from 1<sup>st</sup> Jan 2006)

##### 1 – Inclusion Criterion:

There is only 1: the diagnosis of an intracranial aneurysm with a diameter of at least 25 mm. Thrombus and wall structures also count as part of the aneurysm, so please use MRI, CT and 3D- (or regular) Digital-Subtraction-Angiography for diameter measurement and diagnosis.

##### 2 – Retrospective Inclusion:

Patients that were treated by you in the past (starting from 1<sup>st</sup> Jan 2006) go into the retrospective arm. Please see the patient again for follow-up examinations.

##### 3 – Create a pseudonym (=patient ID):

Character	1	2	3	4	5	6	7	8
"r"	2 <sup>nd</sup> letter of first name	2 <sup>nd</sup> letter of last name	"100" minus last 2 digits of year of birth		your registry center number			the number the patient has on your list of inclusion

!!! For retrospective cases add an "r" to the ID, which then makes it a 9-character-ID. !!!

**EXAMPLE:** Paul Miller, born in 1951, is the 4<sup>th</sup> patient the registry center in Munich (center number "16") includes retrospectively. He receives the ID: r a i 4 9 1 6 0 4.

##### 4 – Basic Module:

Please fill in the "Basic Module" data sheet. Please use the time period of the initial therapy for the "Basic Module".

##### 5 – Follow-Up:

Please search for and document all follow-up examinations conducted in the past using the Follow-Up data sheets and try to stick to the 1, 3 and 5 year follow-up time points as good as possible. If possible, schedule another follow up examination in the present (usually 5 year follow up).

**Patient inclusion:** the only inclusion criterion is the diagnosis of an intracranial aneurysm with a diameter of at least 25 mm. Thrombus and wall structures also count as part of the aneurysm, so please use both MRI (with TOF) and 3D- (or regular) Digital-Subtraction-Angiography for diameter measurement and diagnosis.

**Prospective data collection:** Patients that you have not treated before and now present to you for treatment go into the prospective arm. Please read the patient information form to the patient (or legal representative) and ask to sign the consent form. Please fill in the “Basic Module” data sheet. If an endovascular or surgical therapy is chosen, please use the time period in which the patient is accepted to the ward for therapeutic intervention for the “Basic Module”. For patients you wish to treat conservatively you can use the initial contact with the patient for the “Basic Module”. Please see the patient again for follow-up examinations at 1, 3 and 5 years after inclusion.

**Retrospective data collection:** Patients that were treated by you in the past (starting from 1<sup>st</sup> Jan 2006) go into the retrospective arm. For the “Basic Module” please use the time period of the initial therapy. If the patient was treated conservatively you can use the initial contact with the patient for the “Basic Module”. Please search for and document follow-up examinations conducted in the past using the follow-up data sheets. Of course the 1-, 3- and 5-year follow-up time points cannot be strictly applied in the retrospective arm, but for documentation please try to stick to these time points as good as possible. If possible, schedule another follow up examination in the present (e.g. the 5-year follow-up).

## Basic Module

**create a patient-ID (=pseudonym):** the ID has 8 characters and is constructed from the second letters of the first and last name, "100"- the last 2 digits of the year of birth, the registry-center-number and the number the patient holds on the list of inclusions for each center.

Character	1	2	3	4	5	6	7	8
	2 <sup>nd</sup> letter of first name	2 <sup>nd</sup> letter of last name	"100" minus last 2 digits of year of birth		your registry center number		the number the patient has on your list of inclusion	

**EXAMPLE:** Paul Miller, born in 1951, is the 22<sup>nd</sup> patient the registry center in Munich (center number "16") includes prospectively. He receives the ID: a i 4 9 1 6 2 2.

For retrospective inclusions please add an "r" to the front of the ID, so that the retrospective inclusions actually have 9 characters (e.g. r a i 4 9 1 6 2 2)

**date of presentation:** fill in the date at which the patient presented to your department for the first time due to the current event related to the giant-aneurysm. For prospective cases

that undergo intervention (surgical or endovascular) please use the time point at which the patient is accepted to the ward for therapeutic intervention. For prospective patients you wish to treat conservatively you can use the initial contact with the patient. For retrospective patients please use the time period of the initial therapy.

**reason for presentation (current event):** please specify the clinical characteristics of the current event. Multiple answers are possible. If a *subarachnoid hemorrhage* (SAH) has occurred classify it using the WFNS-scale as follows:

WFNS – Grade	CGS Score	motor deficit
1	15	absent
2	14-13	absent
3	14-13	present
4	12-7	present or absent
5	6-3	present or absent

“*epileptic seizure*” refers to both focal and generalized seizures.

“*effects of local compression by the aneurysm*” describes any symptom caused by mechanical pressure exerted by the aneurysm, e.g. oculomotor-palsy caused by an AcomA-aneurysm compressing the oculomotor-nerve. Lethargy due to a frontal edema caused by an aneurysm also falls into this category. Headache counts as an effect of local compression by the aneurysm only if it can so be classified using the International Headache Society Classification of headaches (ICHD-II; <http://www.ihs-classification.org>).

“*secondary ischemic stroke caused by the aneurysm*” refers to any signs of ischemic stroke caused by the aneurysm, no matter if embolic or direct.

“*asymptomatic / incidental finding*” refers to any patient who has no deficit caused by the aneurysm.

**health condition before current event:** if the patient is unconscious please contact relatives and friends to gather this information. Please classify according to the modified Rankin Scale:

mod. Rankin Score	Condition
0	no symptoms at all
1	no significant disability despite symptoms; able to carry out all usual duties and activities
2	slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	moderate disability; requiring some help, but able to walk without assistance
4	moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	dead

“*Has this aneurysm been diagnosed prior to current event or presentation?*”: this point is especially relevant if the exact same aneurysm had been diagnosed before the current event or current presentation to the hospital, even if it might not have been a giant aneurysm at that point. If this is the case, please also write down the date of that diagnosis.

**risk factors:**

“*hypertension*” is defined as a repeatedly elevated blood pressure exceeding a systolic pressure above 140 mmHg with a diastolic pressure above 90 mmHg or treated with antihypertensive drugs.

“*myocardial infarction*”: please check the cardiological history for this information.

“*additional aneurysms*”: please check the patient’s history for both intracranial and extracranial aneurysms and if they have bled or not.

“*smoker*”: please check smoking history especially for phases of regular smoking and ask whether the patient has quit smoking. “*former smoker*” is defined as a patient who quit smoking more than 6 months ago.

“*alcohol abuse*” is defined based on current literature focusing on alcohol abuse as a risk factor for SAH, which describes a 2-fold increase in relative SAH-risk in patients that consume more than 150 g of alcohol per week, with a more hazardous effect on women. We therefore define “alcohol abuse” as follows:

for men: consumption of more than 2 units of alcohol per day which equals more than 20 grams of alcohol per day. This is more than 1/2 liter of beer (5% alcohol) per day or more than 250 milliliters of wine (10% alcohol) per day or more than 60 ml of wodka, whisky or rum (each about 40% alcohol) per day.

for women: consumption of more than 1 unit of alcohol per day which equals more than 10 grams of alcohol per day. This is more than 250 milliliters of beer (5% alcohol) per day or more than 125 milliliters of wine (10% alcohol) per day or more than 30 ml of wodka, whisky or rum (each about 40% alcohol) per day.

“*polycystic kidney disease / arteriovenous malformation / Ehlers-Danlos-syndrome / Marfan-Syndrome*”: please ask for any of these diagnoses in the patient’s history.

“*family history of aneurysms (1. generation)*” comprises aneurysms of the patient’s parents, siblings or children.

**previous treatment:** please list all aneurysm therapies carried out before the current presentation / event including surgical, endovascular and regular medication.

**health condition at current presentation:** Please fill in the big boxes with both mod. Rankin Score (see above) and Glasgow Coma Score (Points 3 – 15) as follows:

Score	opening of eyes	verbal response	motor response
1	None	None	none
2	to painful stimulus	incomprehensible	extension to painful stimulus
3	when being spoken to	inappropriate	flexion to painful stimulus
4	Spontaneously	disoriented	poorly coordinated pain response
5		Normal	correctly coordinated pain response
6			obeys commands

Please also list whether the patient is asymptomatic or suffering from any of the three neurological deficits listed:

“*cranial nerve palsy*” refers to any cranial nerve deficit, be it singular or including multiple cranial nerves.

“motor deficit (arm/leg)” includes weakness or paresis in arm or leg ranging from mono- to tetraparesis.

“*aphasia*” includes all possible subtypes from moderate motor / sensory aphasia to global aphasia.

**radiologic diagnosis at current event:**

“*SAH*” describes any blood within the subarachnoid space.

“*ICH*” stands for intracerebral hemorrhage and comprises any blood within cerebral parenchyma.

“*SDH*” stands for subdural hematoma and describes any hemorrhage within the subdural space.

“*edema*” describes any peri-aneurysmal swelling of brain tissue that is most likely caused by the aneurysm.

“*ischemia*” describes any sign of hypoperfusion of brain tissue most likely caused by the aneurysm, either embolic or direct.

“aneurysm without additional pathology” applies to patients that have an aneurysm without any radiologically visible additional pathology.

**characterization of the aneurysm:** please document the imaging modes that were used to diagnose the aneurysm (multiple answers are possible) and localize its feeding vessel. Please not that for the measurement of the largest diameter an MRI should be included (with TOF), since thrombosed parts of the aneurysm cannot be visualized using conventional DS-angiography.

“*CT-A*” = Computed-Tomography-Angiogram

“*MR-A*” = Magnetic-Resonance-Angiogram (TOF-sequence also counts as MR-A)

“*DS-A*” = Digital-Subtraction-Angiogram

“*ICA*” = internal carotid artery

“*MCA*” = middle cerebral artery

“*ACA / AcomA*” = anterior cerebral artery / anterior communicating artery. In case of an AcomA-aneurysm please mark “right” or “left” according to the right or left part of the vessel.

“*posterior circulation*” includes the posterior communicating artery, posterior cerebral artery, basilar artery and vertebral artery as well as all cerebellar arteries.

Please also describe the aneurysm’s interior configuration, choosing between “*completely thrombosed*”, “*partially thrombosed*” and “*calcified*”. As mentioned above: MRI helps regarding thrombosis and CT regarding calcification.

**acute therapy:** please document if “*conservative*” therapy was carried out or surgical or endovascular intervention took place. If therapy was conducted surgically or endovascularly

please describe the techniques used to occlude the aneurysm and / or occlude and / or reconstruct the vessel.

“*direct aneurysm occlusion*”: this includes endovascular coiling (e.g. directly or through a stent or others) or direct surgical clipping, e.g. in the case of a saccular aneurysm, or other surgical approaches.

“*vessel occlusion*”: this refers to any occlusion of associated vessels, e.g. proximal occlusion, distal occlusion or both (trapping). Please describe whether vessel occlusion was carried out endovascularly (e.g. with coils) or surgically (e.g. with clip or others (e.g. ligation).

“*vessel reconstruction*”: this refers to the reestablishment of the original vessel structure at the site of the giant aneurysm. Please describe whether vessel reconstruction was carried out endovascularly (eg. using a regular or flow diversion stent) or surgically (e.g. using tandem clipping).

“*ventriculo-peritoneal or –atrial shunt*”: please document whether a shunt was implanted (e.g. in case of hydrocephalus)

“*decompressive craniectomy*”: please document whether decompressive craniectomy was performed

“*bypass surgery*”: please document whether bypass surgery was performed (e.g. for revascularization distal to the aneurysm).

### **complications:**

a) caused by therapy

please document if complications of therapy occurred and if so, differentiate between the following:

“*intracranial bleeding*”: any hemorrhage caused by the therapy itself (including SAH, ICH, EDH and excessive SDH inducing mass effect. Please note that EDH and SDH have to be relevant with mass effect. The usually occurring minimal postoperative EDH or SDH without mass effect does not have to be documented here ).

“*secondary ischemic stroke*”: cerebral ischemic stroke caused by the intervention.

b) occurred during therapy

This includes any complications during therapy that were not directly caused by therapeutic interventions.

“*vasospasm*”: any vasospasm (whether angiographic, measured by transcranial doppler or clinical) is documented here.

“*hydrocephalus*”: any hydrocephalus is documented here, even if aneurysm therapy was carried out conservatively.

### **radiologic result after intervention:**

“*completely occluded*”: the aneurysm is completely excluded from blood flow.

“*incompletely occluded*”: there is remaining perfusion of the aneurysm.

“*flow reversal successful?*”: in case of bypass surgery please mark whether flow reversal was reached.

**health condition at discharge:** Please describe the patient’s condition at discharge using the modified Rankin Scale and address possible neurological deficits.

**Was further intervention conducted regarding the same aneurysm?** If further intervention – whether surgical or endovascular – was conducted after initial intervention and before discharge please write down the date of and the reason for intervention, choosing between “*aneurysm rupture*”, “*residual aneurysm lumen*”, “*hydrocephalus*”, “*leakage from bypass anastomosis*” or “*others*”. Please also describe the kind of intervention conducted.

**patient discharged to / medication at discharge / date of discharge:**

please document the destination of discharge, the medication at discharge and the date of discharge (dd/mm/yyyy).

## Follow-Up Examinations

For prospective cases please see the patient again for follow-up examinations at 1, 3 and 5 years after inclusion.

For retrospective cases the 1-, 3- and 5-year time points for follow-up examinations are merely recommendations. It is absolutely sufficient to document any follow-up you can establish from the data at your clinic retrospectively. If there is the chance, please contact the patient for a follow-up examination in the present (e.g. a 5-year follow-up).

**patient-ID and date of follow-up:**

please document the patient-ID (=pseudonym) that was given to the patient at inclusion and write down the date of the follow-up examination.

**health condition:**

Please list whether the patient is asymptomatic or suffering from any of the three neurological deficits listed:

“*cranial nerve palsy*” refers to any cranial nerve deficit, be it singular or including multiple cranial nerves.

“*motor deficit (arm/leg)*” includes weakness or paresis in arm or leg ranging from mono- to tetraparesis.

“*aphasia*” includes all possible subtypes from moderate motor / sensory aphasia to global aphasia.

Please also classify according to the modified Rankin Scale:

mod. Rankin Score	Condition
0	no symptoms at all
1	no significant disability despite symptoms; able to carry out all usual duties and activities
2	slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
3	moderate disability; requiring some help, but able to walk without assistance
4	moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	severe disability; bedridden, incontinent and requiring constant nursing care and attention
6	dead

**Was further intervention regarding the giant aneurysm conducted since the last examination?**

Please specify if since the last time you examined the patient for the registry any intervention (surgery or endovascular therapy) has taken place concerning the giant aneurysm. If "yes", please document the date of the intervention and give a reason for the intervention and specify which kind of intervention took place.

**Has a rupture of the giant aneurysm occurred ever since the last examination that was not treated surgically or endovascularly?**

This is important in specific cases, for example if the therapists decide that the health condition after an aneurysm rupture is too poor to justify an intervention.

**Has a different intracranial aneurysm been treated since the last examination?**

This is important if another intracranial aneurysm has been diagnosed.