

REQUEST TO SHARE REAL-WORLD EVIDENCE/DATA FOR SECONDARY RE-USE

PROJECT TITLE

RWE-NUMBER

(internal number, not to be completed by applicant)

1. APPLICANT

	INTERNAL (AZMM)	EXTERNAL
DATA RECIPIENT	Naam: Dienst/afdeling: Diensthoofd:	Organisation: Department: Adress: Contact person: E-mail: Phone:
	Medische liaison indien ontvanger geen arts is:	Internal contact person:

2. PROJECT

Purpose of the project:

Retrospective study / phase IV studie

Formeel advies Ethisch comité required, e.g. for publication

In this case also send the study protocol and CVs (principal) investigator(s) with the request.

Data (science) project

Briefly describe the project:

(additional information can be joined in attachment)

Category of data:

- Anonymous data** is data that does not relate to an identified or identifiable natural person, or personal data so made that the data subject is not or no longer identifiable.
- Encoded or pseudonymised data** can only be associated with a patient by means of a code, a pseudonym or a "pseudo-ID". This code or pseudo-ID may have been applied by the person who originally held the data or by a so-called intermediary organization (or "Trusted Third Party").
- Non-coded data** is data that can be associated with the patient.

Does the data set contain sensitive personal data:

- Healthcare data
- Genetic data
- Racial or ethnic data
- Psychological or psychiatric data
- Biometrical data
- Political or philosophical data

Description of data points in the dataset(*):

Sample size (number of individuals, period, ...) (*):

Roles in respect of GDPR

	Data controller <i>(when more than one marked as joint data processors)</i>	Data processor
Institution / Physician	<input type="checkbox"/> <i>Data processing agreement of hospital needs to be completed and signed (template Zorgnet).</i>	<input type="checkbox"/> <i>Please send copy of data processing agreement for review.</i>
Externe applicant (zie 1.)	<input type="checkbox"/>	<input type="checkbox"/>
Other:	<input type="checkbox"/>	<input type="checkbox"/>

Legal ground for processing:

- consent (GDPR art. 9.2a)
- public interest, scientific or historical research or statistical purposes (GDPR art. 9.2j)
- Other:

Way of data transfer:

- Secured cloudservice AZMM
- Encrypted file – File and key are transferred separately.
- Other:

Describe the dataflow (which processing activities will take place **after receipt of the data, by whom and where e.g. local, cloud, ... Where and when are data saved):**

Intention to transfer outside the EEA:

- No
- Yes, please specify:
- Which suitable measures will be taken?
- Binding Corporate Rules
- Standard Contractual Clauses
- Other,

Retention period:

- The dataset, and any copies, will be permanently deleted after the end of the project/retention period.

Timing project**Start date:****End date:**

3. FINANCIËLE OVEREENKOMST - FINANCIAL AGREEMENT

Is this project financially supported by an organisation?

- Yes, by whom? Please attach financial agreement/budget proposal.
- No

Invoicing adress:**TVA number:****Describe the (potential) advantage for hospital if there is no financial agreement:**

- IP on 'result' / product
- Return copy of data / result / registry
- Other:

I declare that the information given is in accordance with reality.

I declare, taking into account minimal data processing (GDPR), that the requested data is sufficient, relevant and limited to what is necessary for the described purposes.

	INTERNAL (AZMM)	EXTERNAL
DATA RECIPIENT	Datum: Naam: Handtekening:	Date: Name: Signature:
	Datum: Diensthoofd: Handtekening:	
	Medische liaison indien ontvanger geen arts is: Datum: Naam: Handtekening:	Internal contact person: Date: Name: Signature: