

## Procedure for using GIANTT-data by a third party

1. For conducting research making use of data from the GIANTT Database, a written request should be sent by the applicant(s) to the projectleader of GIANTT (see appendix 1, *GIANTT data request form*). The request will be evaluated by the GIANTT steering committee, consisting of representatives of data provider parties (health care providers and patients) and the University Medical Center Groningen (UMCG). The research proposal will be evaluated against the overall goal of GIANTT, *i.e.* to improve the quality of care delivered to patients with type 2 diabetes mellitus (see also [www.giantt.nl](http://www.giantt.nl)), and the agreements made with the data providers. For this, the steering committee assesses the scientific quality and feasibility of the study. Furthermore, the steering committee will monitor possible conflicts arising from the research request that may overlap with running or other planned research making use of the GIANTT data.
2. Before data can be used for scientific research, an approval should be received from the GIANTT steering committee. Requests will be presented in writing to all members of the committee. Objections raised in this phase will be communicated to the applicant(s). When objections remain after revision, the request will be discussed with the steering committee striving for a unanimous judgment. The applicant(s) will be informed of approval or rejection with stated reasons. If the representative of the Groninger Huisartsen Cooperatie (GHC) deems it necessary, the decision about the use of data from the general practitioners contracted by the GHC can be submitted to the GHC board. When needed the GHC board and the daily management of the GIANTT steering committee will discuss whether approval from individual practitioners is needed.
3. After a request has been approved by the GIANTT steering committee, agreements will be made with the data recipients regarding the appropriate and restricted use of the data (for scientific research as defined in the data request), publication of results (source, co-authorship, right to inspect and correct scientific inaccuracies), and costs made for preparing the dataset (see appendix 2, *Data recipient agreement for GIANTT data*). If needed, agreements can be made about informing the data providers.
4. When individual approval is needed from the data providers, GIANTT will try to combine such requests.

## Appendix 1 GIANTT Data request form

<i>GIANTT number</i> <i>Date receipt</i>	<i>Will be completed by GIANTT</i>
Applicant/Supervisor Organization Address Phone e-mail	
Title research	
Financer	
Others involved	
Short description of background, aim and specific research questions	
Methods  - design  - study population (in/exclusion criteria of patients also regarding date of diagnose and time for follow up)  - definition of determinants and outcomes and data needed from GIANTT (desired aggregation level, time period relevant to all data)  - planned additional data collection	
Plan  - global timeline	

### Completed by GIANTT

Afhandeling door GIANTT Stuurgroep (SG)

	datum	Opmerkingen
Verzoek binnengekomen		
Schriftelijk voorgelegd		
Reakties		
Bevestiging goedkeuring		
Bijzondere voorwaarden		
Afspraken met aanvrager		

## Appendix 2. Data recipient agreement for GIANTT data

These terms and conditions apply to the GIANTT Data Request Form and form part of the data recipient agreement (application number .....).

1. The applicant will receive the singular and limited right of use of the data provided. This means that the recipient may only use the data provided for the purpose for which they were requested in the GIANTT Data Request Form that was approved by the GIANTT steering committee.
2. The right of use is limited to the period in which such use is necessary to realize the agreed-upon purpose. When this period is not stated in the Data Request Form, it is set at 12 months after receiving the data. If needed, a request can be made to extend this period. The applicant is required to destroy the data within 3 months following the expiration of the temporary right of use. The recipient is required to provide a signed document to ascertain that the data, including any copies, have been completely and permanently deleted. GIANTT will store a copy of the original dataset and, if needed, any derived datasets for future inspection or monitoring purposes.
3. GIANTT does not guarantee that the data are fully suitable for the purpose for which the applicant wishes to use them.
4. The applicant may not allow other parties to use the data or provide any of the data to other parties, unless GIANTT has given written permission to do so.
5. The applicant must take adequate security measures in the processing and storage of the data provided, and secure the data against loss and unauthorized use.
6. When relevant, all persons handling data obtained from GIANTT must sign a secrecy agreement.
7. The applicant will send any publications using data obtained from GIANTT to the projectleader of GIANTT before publication, for inspection and correction of scientific inaccuracies.
8. The applicant is required to include the following citation in all communications or publications using data obtained from GIANTT: *"Data were obtained from the Groningen Initiative to Analyse Type 2 Diabetes Treatment (GIANTT) database. The GIANTT database contains anonymized longitudinal information retrieved from electronic medical records of general practitioners and is maintained by the University Medical Center Groningen [1]. 1. Voorham J, Denig P. Computerized extraction of information on the quality of diabetes from free text in electronic medical patient records of general practitioners. J Am Med Inform Assoc. 2007;14(3):349-354."* For input on data selection, retrieval, cleaning, analysis and/or interpretation, Prof dr P Denig must be consulted as potential co-author.
9. Additional agreements can be made regarding co-authorship on publications using data obtained from GIANTT.
10. The applicant is obliged to pay a fee for the provision of data. This fee is based on costs made for preparing the dataset, and will thus depend on the amount and complexity of the required data.
11. The right of use can be immediately terminated by written notification from GIANTT, without any liability for possible damages, when:
  - a. the applicant is declared bankrupt or discontinues its activities;
  - b. the applicant does not comply with any of the above terms or conditions.

### Representing the applicant and/or data recipient,

Name:

Function and affiliation:

Date:

Signature: