

CompCure ERKReg-Subregister Prospective cohort study on C3G and IC-MPGN

OBJECTIVE

The overall objective of CompCure is to drive better outcome in **C3G and IC-MPGN**.

To do that an international registry is established to develop a stronger evidence base that will inform clinical decision-making.

CompCure will provide evidence on:

-  Defining the natural history of C3G
-  The diagnostic and prognostic role of complement biomarkers
-  Better ways to arrive at a correct diagnosis
-  Personalized, targeted treatment approaches
-  Getting access / matching patients to new trials
-  Monitoring of safety and efficacy of new drugs

The registry is collecting **clinical, biochemical and genetic data**.

In addition, a **histopathology archive** is established with C3G and IC-MPGN kidney biopsies, as well as a biobank.

PATIENT ENROLMENT

Eligibility Criteria

- Age 0 to 90 years
- Newly diagnosed (INCIDENT) patients with C3G/IC-MPGN
- PREVALENT patients if information from time of disease onset available
- Diagnosis confirmed by kidney biopsy
- Excluded: Secondary MPGN

STUDY PROCEDURES

1. **Registry eCRF entries: ERKReg Subregistry, detailed information on immunodiagnosics**
 - At enrolment
 - Annually
 - At time of any change in treatment and 3 months thereafter
2. **Sampling for Biobank:**
At enrolment and annually
3. **Submitting histopathology slides:**
At enrolment and in case of re-biopsy

CompCure welcomes participation from centers who can process, store and send biosamples, and who has a local pathology institute who can digitalize and send histopathology slides.

PAPERWORK TO GET YOU STARTED:

Non-ERKNet Centers:

SUBMISSION of the following documentation to your local ethics committee:

- ERKReg Protocol
- Ethics approval from Heidelberg EC
- Informed consent for ERKReg Register

All centres:

SUBMISSION of the following documentation to your local ethics committee:

- Study Protocol
- Ethics approval from Heidelberg EC
- Participation in the ERKReg registry
- Addendum to data sharing agreement for CompCure (to be signed and sent back)
- Separate informed consent for cohort study with biobanking!

COMPCURE OFFERS COMPLEMENTARY CENTRALIZED DIAGNOSTIC SERVICES

- Complement/autoimmune panels in reference laboratories in Bergamo, Gdansk, Heidelberg, Nijmegen, Madrid and Paris
- Centralized genetic screening
- Reference pathology
- Financial support to participating centers for each patient enrolled

ERKReg				compCure			
Core Registry: 470 patients				Sub-Registry: 100 patients			
	Children	Adults	Total		Children	Adults	Total
All	166	264	430	ERKNet	14	8	22
IC-MPGN	62	130	192	Comp	5	2	7
C3G	112	134	246	Diagn	9	6	15
Diagn	14	17	31	Diagn	9	6	15
Diagn	114	119	233	Diagn	9	21	30

➤ **HOW TO JOIN THIS PROJECT?**

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