

# Registration process



Different levels of documentation can be chosen for the different disease groups (e.g. a centre chooses level 2 only for Antibody deficiencies and Complement deficiencies and level 1 for all others). Level 3 forms will be added later for dedicated studies.

There are two basic types of forms:

- Global forms:
  - exist only once per patient
  - can also be list forms containing several entries
- Date-dependent forms (=current data forms)
  - exist once per documentation date

# Relevant Forms Level 1

- Global forms:
  - Patient info
  - Way to Diagnosis
  - PID Diagnosis (list)
  - HSCT and Gene Therapy (lists)
  - Death report form
- Date-dependent forms (=current data forms):
  - Current status
  - Current treatment:
    - Ig-Replacement

# Relevant Forms Level 2

- Global forms:
  - Patient info
  - Way to Diagnosis
    - + Clinical Manifestations
    - + Laboratory values
  - PID Diagnosis (list)
  - HSCT and Gene Therapy (lists)
    - +possibly further details on HSCT and gene therapy
  - Death report form
  - Malignancies (list)
- Date-dependent forms (=current data forms)
  - Current status
  - Current clinical manifestations
  - Quality of Life
  - Current laboratory values
  - Current treatment:
    - Ig-Replacement
    - Other treatments (antibiotics, immunosuppressives, PEG-ADA, G-CSF...)

# Data forms and levels

**Level 1**

**Level 2**

To be documented at baseline only

Patient Info

Way to diagnosis+  
PID Diagnosis

Clin. manifestations  
from birth to dx

Lab values leading  
to initial dx

To be documented at baseline and every follow-up

Current status

Current Ig-Repl.

Current  
Therapy

Current lab  
values

Any changes to  
Diagnosis, any new  
HSCT or gene  
therapy?

HSCT,  
Gene therapy

QoL

Clin. manifestations

Malignancies

- **Level-1 Documentation**

- At initial registration: Basic diagnostic data, H SCT/gene therapy and current Ig replacement at initial registration

**AND**

- In every subsequent calendar year: Changes to living status or diagnosis, H SCT/gene therapy/ Ig replacement update

- **Level-2 Documentation**

- At initial registration: Complete diagnostic data, current therapy, QoL; if diagnosis > 12 months ago: current Clinical manifestations, lab values

**AND**

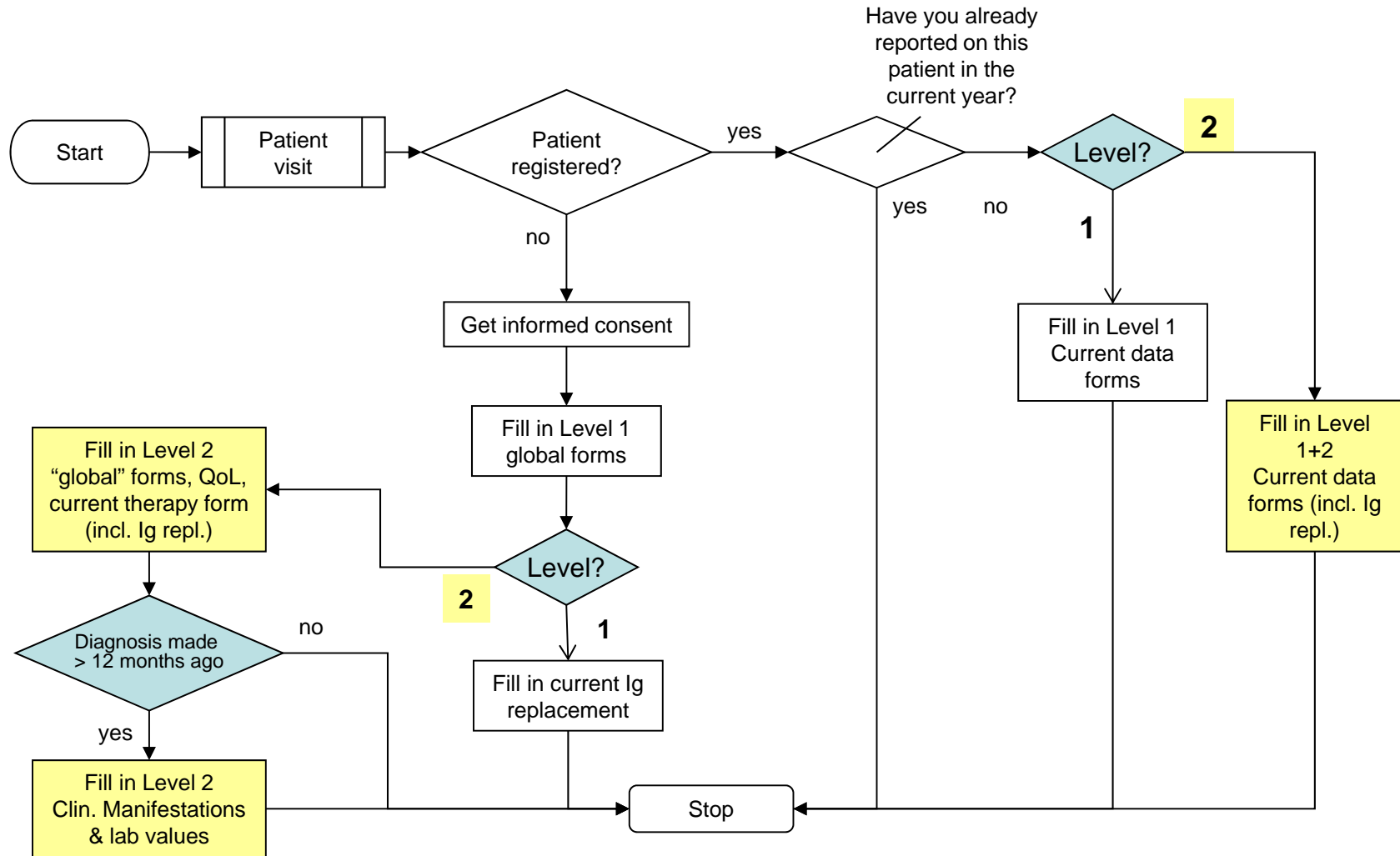
- In every subsequent calendar year: Current clinical manifestations, lab values, therapy, QoL (only if news are available)

- **Comments:**

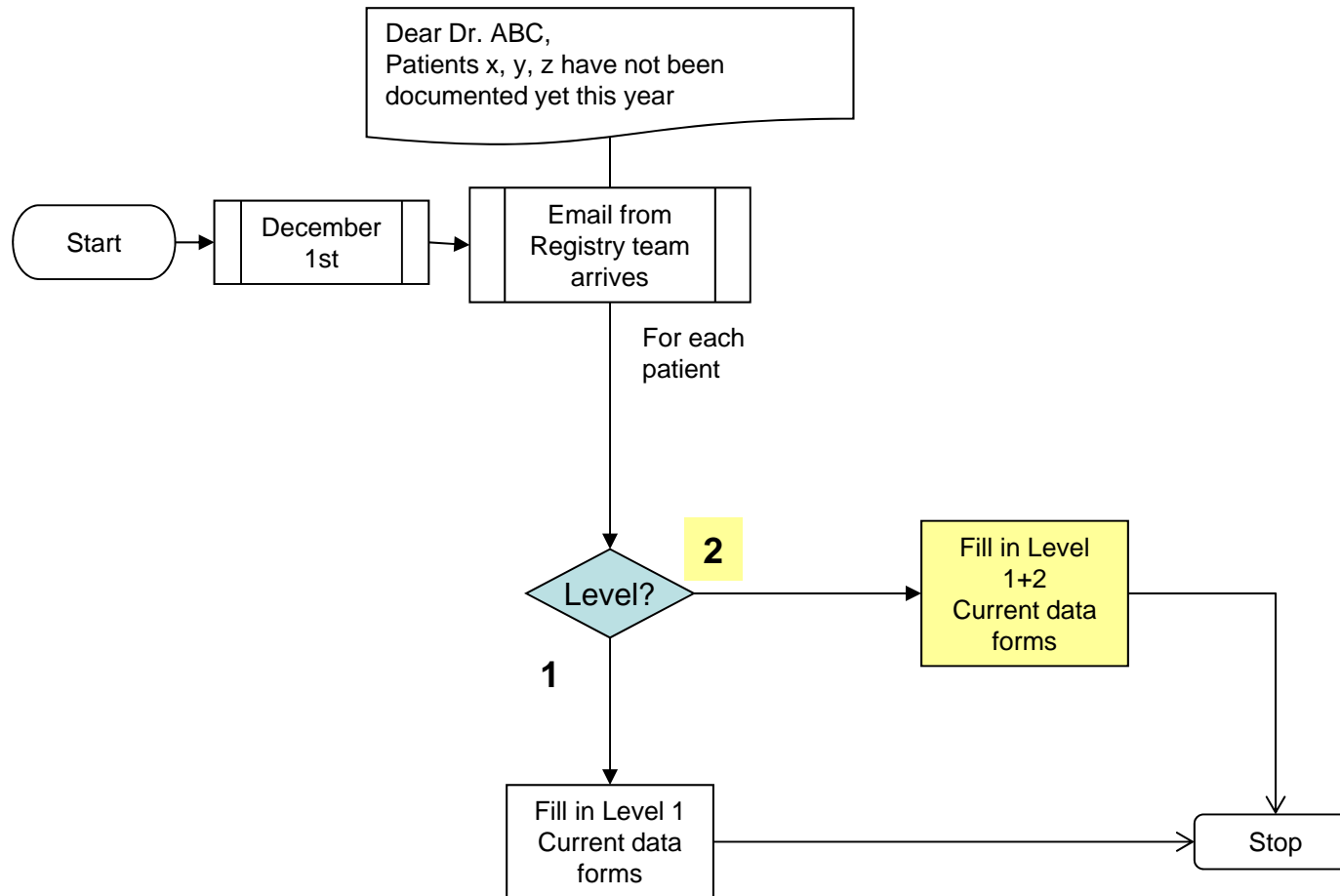
- For deceased patients, the “death report form” must be filled in

The following flowcharts describe the documentation process for each documenting centre

# Patient visit



# Annual reminder





# Option “patient questionnaire” For new calendar year (level 2)

