Criteria for a Leukemia Cytogenetics Registry

- data collection is part of a clearly defined project
- agreement about a minimal data set
- measures for quality assurance are available

Strategy to set up a project

- Define the aim of the study
- Define collaborators
- sign a confidentiality agreement

Agreement about confidential collaboration

- rules about the use of data
  - all rights remain with the responsable investigator
  - access to the data for all contributing investigators
  - coauthorship according to defined criteria
  - no use of data without written consent of the responsable investigator
  - deletion of cases from a central database upon request of the responsable investigator

Minimal Data Set

Minimal dataset **Patient data**

- patient identification no. of the study
- patient identification no. of the cytogenetic laboratory
- age at time point of investigation
- sex
- country of the referring clinic
- ZIP code of the referring clinic
- name of the referring clinic

Minimal dataset **Sample data**

- date of sampling
- date of sample receipt
- type of sample
- type of chromosome banding

Minimal dataset **Cytogenetic findings**

- date of report
- complete karyotype according to current ISCN
- banding resolution of the aberrant metaphases (banding resolution of the normal metaphases, if only normal metaphases are present)
- name of the investigating cytogenetic laboratory
- name of the responsable investigator

Cytogenetic data quality assurance

- Retrospective clinical studies:
  - documentation of karyotypes in data file by responsable investigator of the investigating laboratory
  - Data exchange electronically only to prevent from type writing errors
  - Plausability and type writing errors checked by responsable cytogeneticist of the study

Cytogenetic data quality assurance

- Prospective study
  - Record if central karyotype review