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 responsible investigator
  - access to the data for all contributing investigators
  - coauthorship according to defined criteria
  - no use of data without written consent of the responsible investigator
  - deletion of cases from a central database upon request of the responsible 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 responsible investigator
Cytogenetic data quality assurance

• Retrospective clinical studies:
  – documentation of karyotypes in data file by responsible investigator of the investigating laboratory
  – Data exchange electronically only to prevent from type writing errors
  – Plausability and type writing errors checked by responsible cytogeneticist of the study
Cytogenetic data quality assurance

• Prospective study
  – Record if central karyotype review