Quality of Life in CML patients -Projects of the German CML Study Group

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German CML study group QoL project - Phase I

CML studies I-IV: more than 4000 patients randomized

2000 patients are alive and will be contacted

| Three patient cohorts: | |
|---|---------|
| – 1-3 years survival | ca. 490 |
| – 4-7 years survival | ca. 740 |
| – 8 and more years survival | ca. 770 |

Number of patients in treatment groups

| | 1 | 2 | 3 | 4 | 5 | 6 | |
|-------------------------------|-----------------|-------------------------|--------------------------|-----|-----|------------|-------|
| Therapy group | 1st imatinib | 1st IFN 2nd imatinib | 2nd generation TKI | SCT | IFN | HU / other | total |
| cohort (years survival) | | | | | | | |
| 1-3 | 461 | 0 | 21 | 5 | 0 | 0 | 487 |
| 4-7 | 464 | 63 | 35 | 121 | 58 | 0 | 741 |
| 8 - 20+ | 2 | 122 | 16 | 513 | 87 | 29 | 769 |

Phase I - objectives

main subject:

 differences in QoL of transplanted patients / patients with TKI (survival is equal in transplanted / TKI patients, however, there is a better molecular remission in transplanted patients, Saussele et al. Blood 2009)

other subjects:

- differences in QoL of first- and second line TKI patients
- late effects in transplanted patients compared to TKI patients
- influence of patient specific parameters (age, sex, ...)

Phase II – objectives

→ differences in QoL of CML patients that are subject to different therapies?

→ Is QoL changing during treatment? (evaluation at diagnosis, after 12 and 24 months)

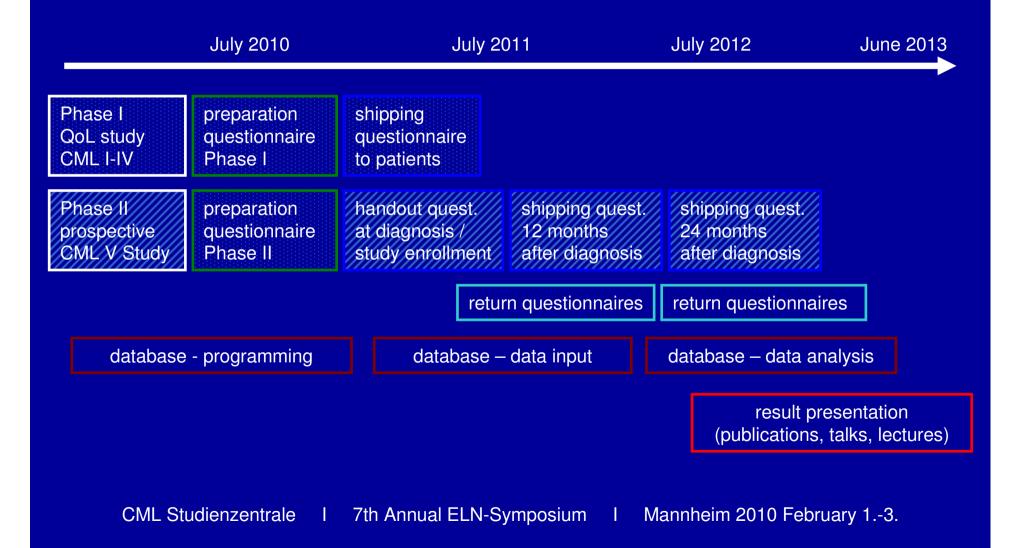
- specific questionnaires
- prospective evaluation

Phase II – CML V study

Integration of a QoL questionnaire in the **CML study V**

 Recruitment: 200 patients per year
 nilotinib vs. nilotinib + interferon alpha (induction / maintenance)

Time table



... the end.

Thank you for your attention! Interested in cooperation?

... the beginning ?