

# CLL trials registry for improvement in the long-term follow-up of CLL patients in European Trials: an ERIC Initiative

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# Need of a CLL Clinical Trials Registry

Long-term FU is needed because of:

- Data on OS needed → the most important end-point!
- Data on response to relapse treatment needed
- Development of resistant genotypes (i.e. p53 deletion)
- Data on secondary diseases (neoplasia, cardiac disease, etc. needed to avoid another VIOXX)
- Indications that the EMEA may demand long-term FU

Problems with long-term FU (IITs and company-sponsored trials) :

- Extremely expensive to keep a trial open
- Enthusiasm wanes as Investigators move onto next trial
- No further FU after primary endpoint was met
- Results of after initial publication are rarely reported

# Concept of the CLL Clinical Trials Registry

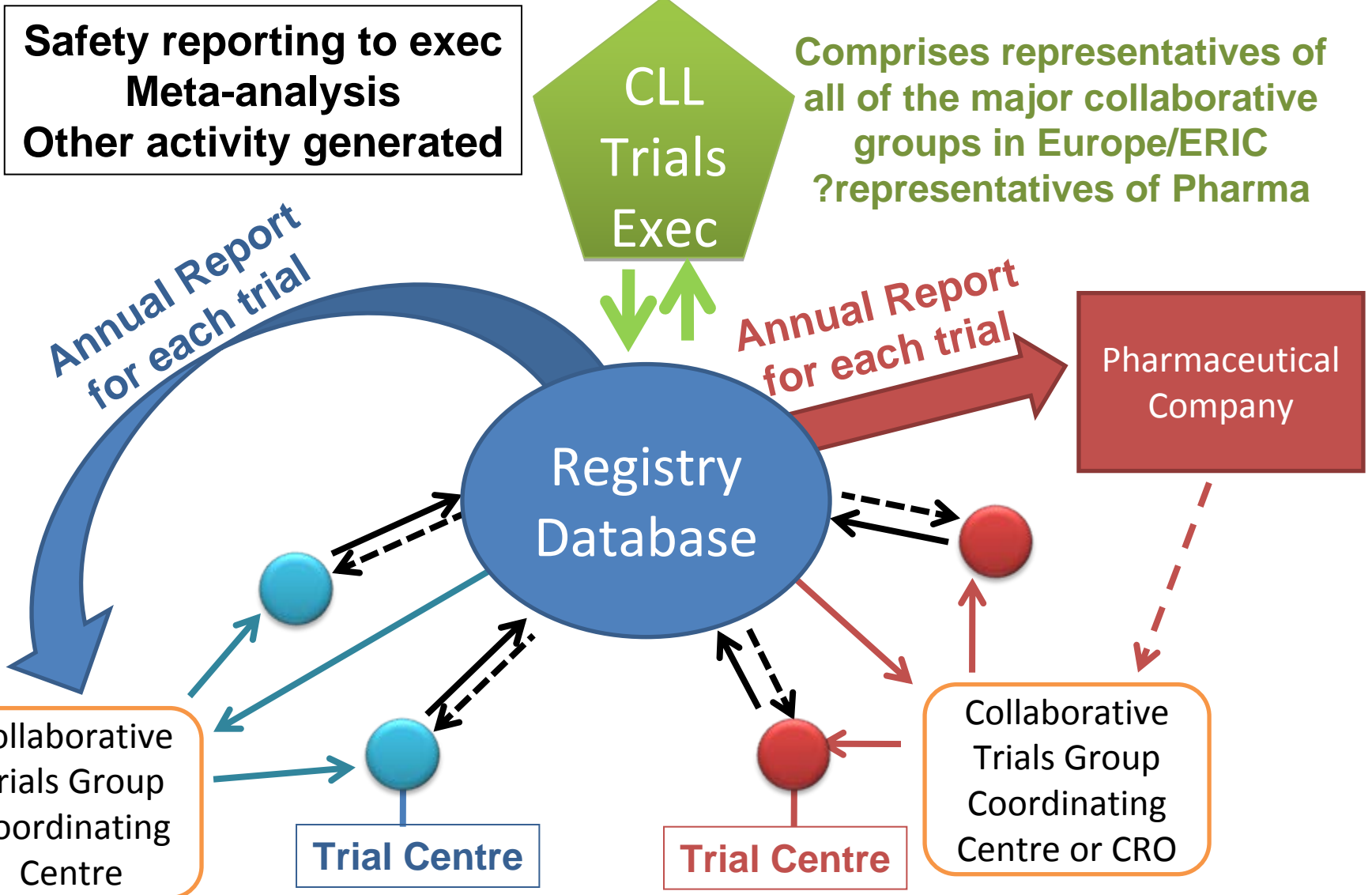
## Purpose of registry:

- Offering long-term FU service
- Allowing wider analysis including meta-analysis and assessment of responses to subsequent treatments

## Concept:

- Web-based system with simple Registry data annually
- National register/ co-ordinating centre
- European Head of register
- ERIC as legal entity is the contract partner for the national registers

# Structure of the CLL Clinical Trials Registry



# Data collection

- Primarily web-based, but paper is also possible.
- Language: primarily english with categorical lists in different languages.
- Time point of register:
  - When primary endpoint was reached (for company initiated trials)
  - From randomization
- Data transfer of original trial database including a minimal data set defined by the IWCLL:  
Diagnosis, stage, age , Risk factors, treatment regimen, response, PFS.....

# CRF: annual FU

| Current Status of Patient   |  |       |       |      |  |  |  |     |       |      |  |  |  |
|---|--|-------|-------|------|--|--|--|-----|-------|------|--|--|--|
| <p>If patient is alive, please specify stage of CLL disease:</p> <p>Did any secondary disease occur?</p>  | <input type="checkbox"/> yes<br><input type="checkbox"/> no → If "no", please complete "Death Report" (D)  |       |       |      |  |  |  |     |       |      |  |  |  |
|   | <input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> SD <input type="checkbox"/> PD → If "PD", please give date of PD <table border="1" style="float: right; margin-left: 20px;"> <tr> <td style="width: 20px;">Day</td> <td style="width: 20px;">Month</td> <td style="width: 20px;">Year</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </table>   | Day   | Month | Year |  |  |  |     |       |      |  |  |  |
|   | Day  | Month | Year  |      |  |  |  |     |       |      |  |  |  |
|   |  |       |       |      |  |  |  |     |       |      |  |  |  |
| <input type="checkbox"/> yes → If "yes", please give date of first diagnosis of secondary disease:<br><input type="checkbox"/> no <table border="1" style="float: right; margin-left: 20px;"> <tr> <td style="width: 20px;">Day</td> <td style="width: 20px;">Month</td> <td style="width: 20px;">Year</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </table> <p>Please specify secondary disease:</p> <input type="checkbox"/> Transformation<br><input type="checkbox"/> MDS/AML<br><input type="checkbox"/> Skin cancer<br><input type="checkbox"/> Autoimmune disease<br><input type="checkbox"/> Rheumatoid arthritis<br><input type="checkbox"/> other | Day  | Month | Year  |      |  |  |  |     |       |      |  |  |  |
| Day   | Month  | Year  |       |      |  |  |  |     |       |      |  |  |  |
|   |  |       |       |      |  |  |  |     |       |      |  |  |  |
| (New) CLL-Treatment   |  |       |       |      |  |  |  |     |       |      |  |  |  |
| <p>Patient received (new) treatment for CLL-disease since last presentation?</p>  | <input type="checkbox"/> yes<br><input type="checkbox"/> no<br>If "yes", please specify: <ul style="list-style-type: none"> <li>• Type of therapy:               <ul style="list-style-type: none"> <li><input type="checkbox"/> Chemotherapeutic therapy</li> <li><input type="checkbox"/> other</li> <li><input type="checkbox"/> radiotherapy</li> </ul> </li> <li>• Reason for new therapy:               <ul style="list-style-type: none"> <li><input type="checkbox"/> progressive disease</li> <li><input type="checkbox"/> other, please specify: _____</li> </ul> </li> <li>• Response to therapy:               <ul style="list-style-type: none"> <li><input type="checkbox"/> CR <input type="checkbox"/> PR <input type="checkbox"/> SD <input type="checkbox"/> PD</li> </ul> </li> </ul> |       |       |      |  |  |  |     |       |      |  |  |  |
| <p>• Start of new therapy: <table border="1" style="float: right; margin-left: 20px;"><tr><td style="width: 20px;">Day</td><td style="width: 20px;">Month</td><td style="width: 20px;">Year</td></tr><tr><td> </td><td> </td><td> </td></tr></table></p> <p>• Stop of new therapy: <table border="1" style="float: right; margin-left: 20px;"><tr><td style="width: 20px;">Day</td><td style="width: 20px;">Month</td><td style="width: 20px;">Year</td></tr><tr><td> </td><td> </td><td> </td></tr></table></p> <p>Completed <input type="checkbox"/></p>  |  | Day   | Month | Year |  |  |  | Day | Month | Year |  |  |  |
| Day   | Month  | Year  |       |      |  |  |  |     |       |      |  |  |  |
|   |  |       |       |      |  |  |  |     |       |      |  |  |  |
| Day   | Month  | Year  |       |      |  |  |  |     |       |      |  |  |  |
|   |  |       |       |      |  |  |  |     |       |      |  |  |  |
| <p>All data on this page have been entered under my authority and to the best of my knowledge are accurate and complete.</p>  |  |       |       |      |  |  |  |     |       |      |  |  |  |

# CRF: Death report

| DEATH REPORT                                    |   |                          |  |  |
|---|---|--------------------------|--|--|
| Intern Study code _____<br>EUDRACT-number _____ | No. of center<br> _ _ _   | No. of patient<br> _ _ _ | Patient's initials<br> _   _ <br>for   name for   name | Date of death<br> _ _   _ _   _ _ <br>Day Month Year |
| Primary cause of death:                         | <input type="checkbox"/> Progressive disease<br><input type="checkbox"/> Infection<br><input type="checkbox"/> Secondary disease<br><input type="checkbox"/> Other, please specify<br><hr/> |                          |  |  |
| Relationship of death to last treatment:        | <input type="checkbox"/> unrelated<br><input type="checkbox"/> remote<br><input type="checkbox"/> possible<br><input type="checkbox"/> probable   |                          |  |  |
| Was autopsy performed?                          | <input type="checkbox"/> yes<br><input type="checkbox"/> no<br><br>If yes* please summarize findings:<br><hr/> <hr/> <hr/> <hr/>  |                          |  |  |

# Ethics and Regulatory Issues

- Ethical approval for standard patient registration and consent form
- Patient consent form
  - at entry into original trial
  - At time point of entering the registry
- Contract between ERIC and study group/Commercial partner re: use of data
  - In principle data still reported by the original organisation
  - For use of non-owned data application to the the executive committee is necessary.