

# **Trials and Tribulations with ePRO**

Rainer Richter



## **Trials and Tribulations in ePRO**

- Decision on ePRO
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- Design phase
- Our first trial
- Conclusion
- Future plans

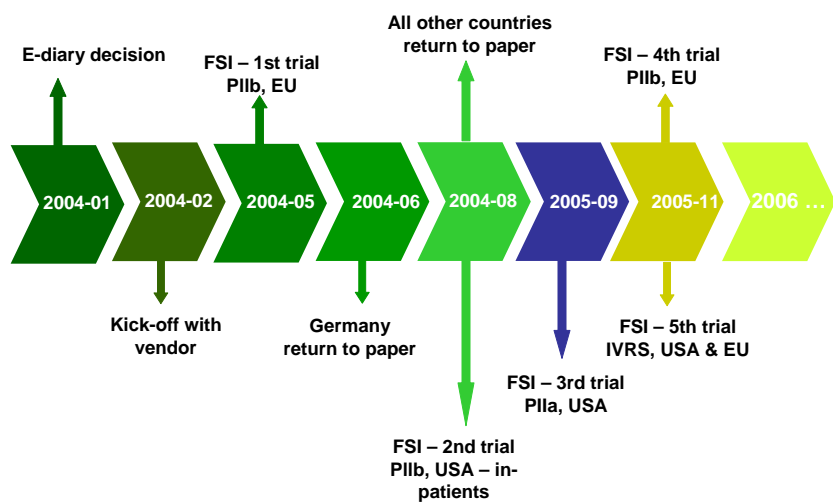
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## Decision on ePRO

- Our way to e-diary
  - Collected information about e-diary
  - Presentations from different vendors
  - Decision to use e-diary to get first experiences

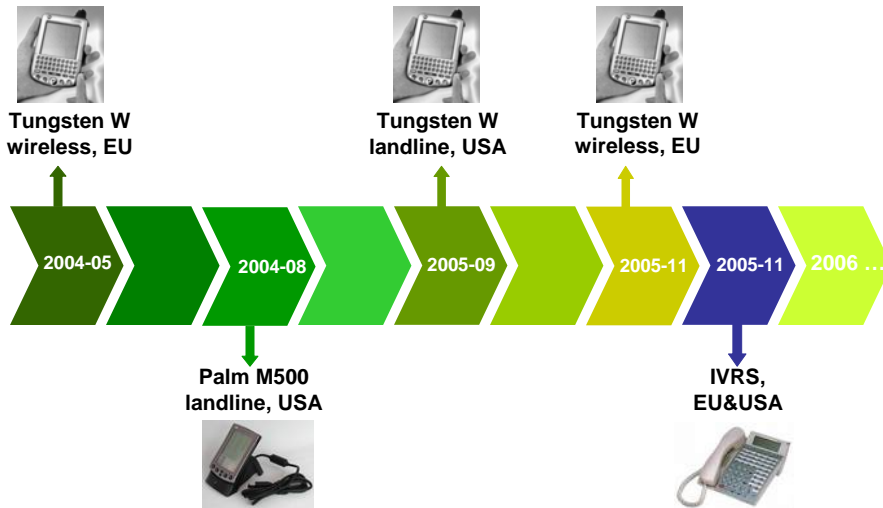
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## Summary of experience



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## Summary of experience (technology)



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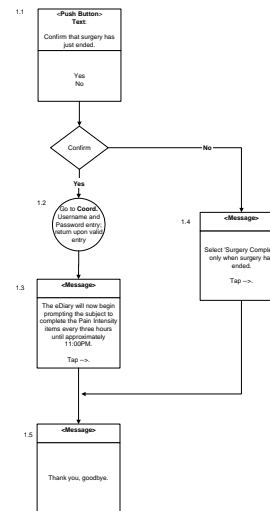
## Design phase

- What have we learnt?
- Study protocol
  - Do not finalize until you have thought about your e-diary design
  - Try to describe as detailed as possible

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## Design phase

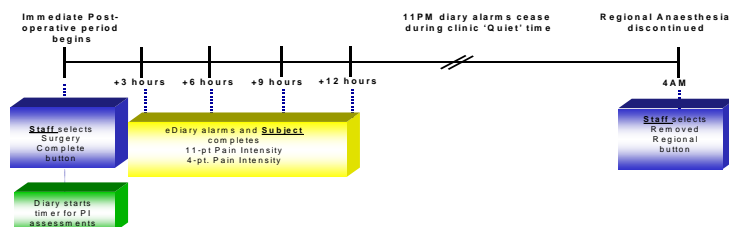
- Develop detailed workflow that you understand



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## Design phase

- Develop detailed workflow(2)



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## Design phase

- Define specifications
  - Be exact – create an internal check list of points to be decided e.g.
    - time windows (when are answers allowed)
    - alarms (and how often should they be repeated)
    - exact wording of questions
    - wording of error messages (for incorrect or missing entries)
    - exactness of time entries (one minute, 5 minutes or 15 minutes?)

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## Design phase

- Translations
  - Check all translations on the screens and by a native speaker
  - (to avoid mistakes like these examples show)

**Report Rescue**

Please enter the time and amount of rescue medication taken:

Time: 10 : 20

Number of tablet(s): 1

Back Next

English

**Eingabe der Rettungsmedikation**

Bitte geben Sie die Einnahmezeit und Einnahmemenge hier:

Uhrzeit: 15 : 00

Anzahl eingenommene: 1

Zurück Weiter

German

Missing text

**Prise du médicament de secours**

Veuillez entrer l'heure de prise du médicament de secours et le nombre

Heure: 03 : 00

Nombre de comprimé(s): 1

Retour Suivant

French

Wrong bracket

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## Design phase

- User Acceptance Test (UAT)
  - test all assessments and features
  - for wireless:
    - Involve local personnel (e.g. CRA) in UAT of the countries where the devices will be used and try data sending
  - do not release UAT until all findings are solved and re-tested
  - insure sufficient time for UAT in project plan (we have always needed 3 rounds)

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## Our first trial

- First problems occur:
  - Data sending in Germany
    - devices could not connect to a provider
    - data sending was not possible with the connected provider
  - Solution: switch to paper in Germany
    - no back-up paper diary available
    - ad hoc creation of paper diary in Germany

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## Our first trial

- More problems:
  - complaints about help desk
  - planned assessments did not occur on the device (only discovered through extensive paper monitoring by a very alert CRA)
  - hardware problems, devices run out of battery and lost diary software)
  - data sending difficulties in other countries

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## Our first trial

- Solutions
  - direct access to help desk (web interface)
  - data check to evaluate the impact of missing data
- finally
  - switch to paper diaries for all countries
    - again urgent setup of paper diaries in local languages required

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## Conclusion

- Early vendor selection for a study
- Detailed specifications
- Extensive UAT  
(until all problems are solved)
- Although we have mixed experiences  
ePRO will be state of the art

## Future plans

- To use e-diaries for all studies with PRO
  - Unless size or design of study suggests otherwise
- IVRS or handheld – both options are possible
- Will use handhelds in coming phase III trials with around 3000 subjects