

EORTC
**Update on the activities of the Quality of
Life Department**

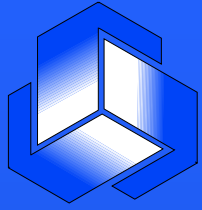
Andrew Bottomley Ph.D

Assistant Director, EORTC

Head, Quality of Life Department, Brussels

September 2008





EORTC Headquarters

- Major changes in management and structures have been completed. New management structures, new methods of working and increased collaboration with industry
- Increased registration trials with and submitted for approval FDA and EMEA, always with QOL (e.g. 18991)
- EORTC HQ continues to evolve, we now have 170 staff, some 16 nationalities, network of 2000 clinicians
- EORTC continues to thrive under pressure

EORTC Quality of life Department: Key Tasks

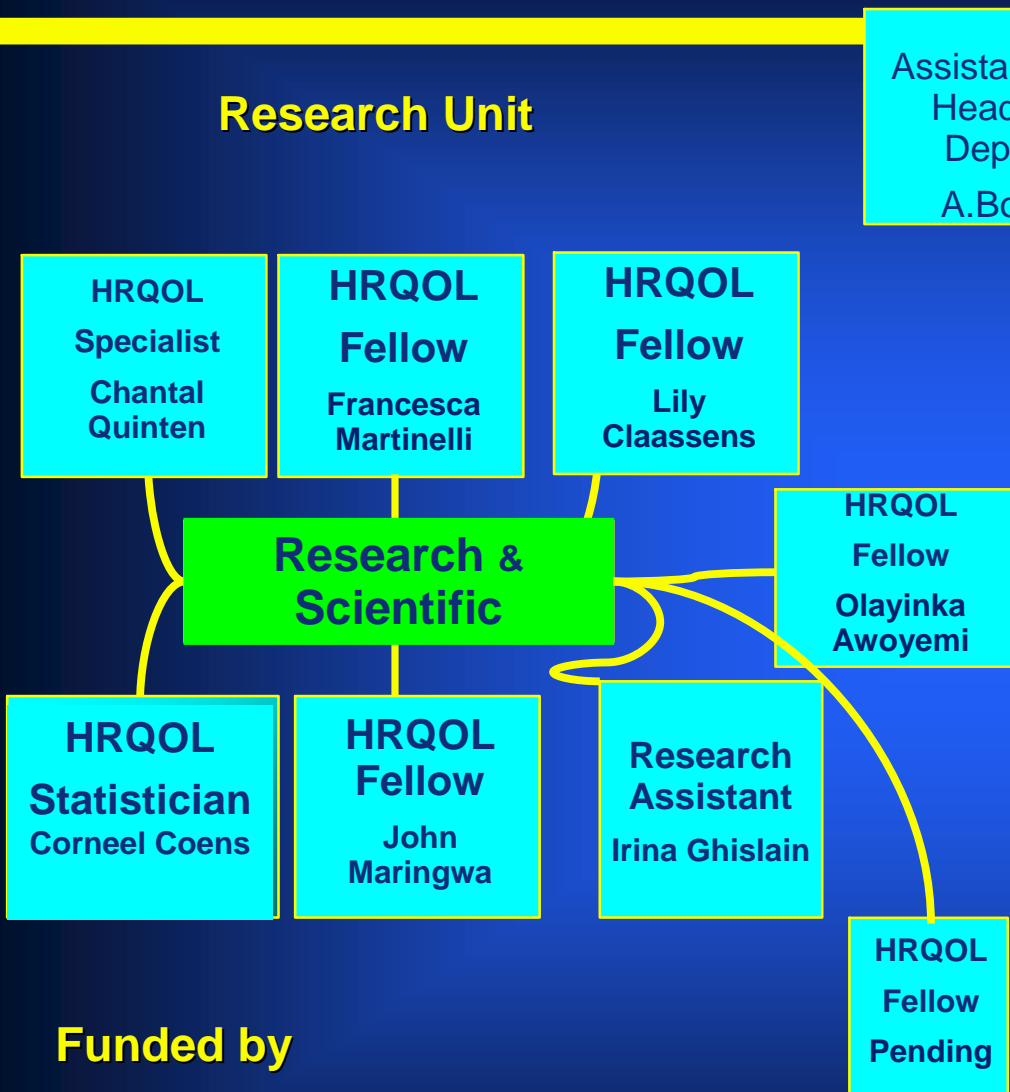
- To supervise the design, conduct and evaluation of QOL in selected cancer clinical trials
- Develop scientific research to help implement QOL in EORTC trials
- To collaborate with the QLG on **joint scientific** initiatives to develop tools (direct and indirect)

WITH THE QLG KEY TASKS ARE:

- Manage the **translation programmes, Item Bank, academic users** and all **pharmaceutical contracts**

Structure of the QOL Department in 2008

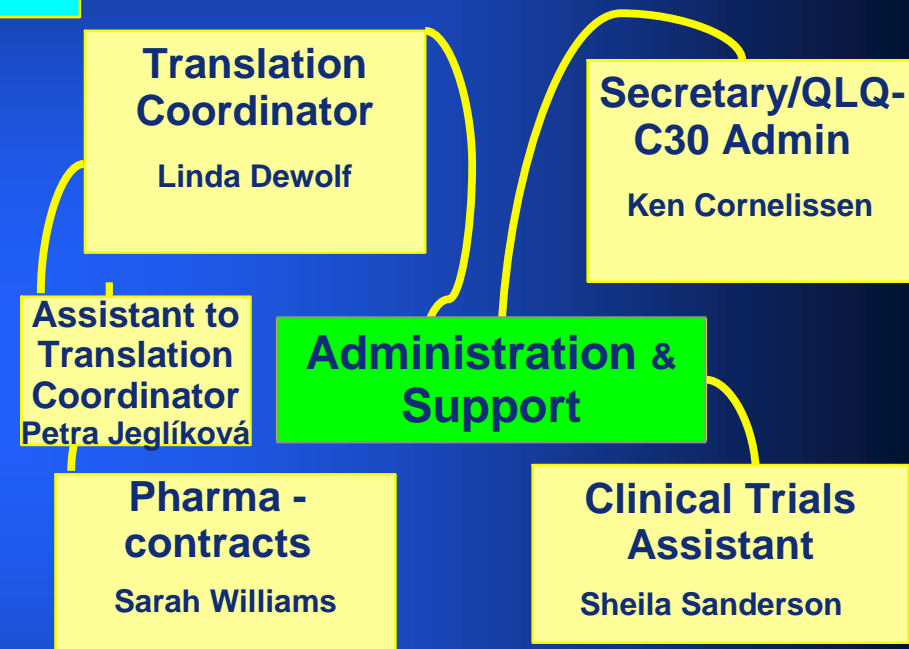
Research Unit



Funded by

■ scientific staff funded by independent research foundation grants and core support TOTAL = 8 FTE

Admin Unit



Funded by

■ QLG funded position
TOTAL 3.1 FTW

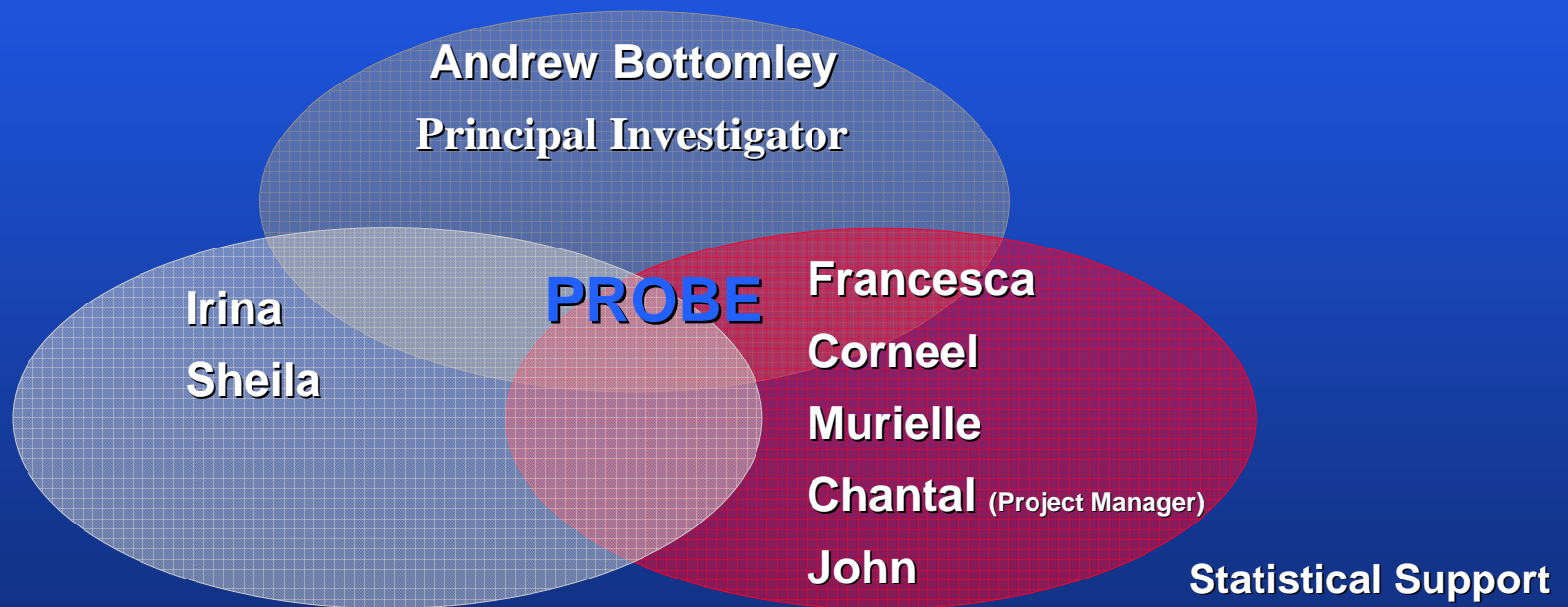
Scientific activities of the department

Funded by EORTC Headquarters and independent peer reviewed grants or from clinical group grants

- The QLG rarely fund QLD research, in part due to QLD focus on clinical trial research and QLG field studies now external from HQ
- Fundamentally now with clinical trials groups in EORTC on trial results as our output. e.g. 18991, 26954, 10081, etc
- Other methodological analysis and QOL research but very limited focus on module development studies
- Department self sustaining with major support major for research programmes e.g. **PROBE** and various grants

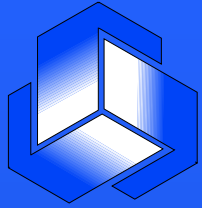
Patient Reported Outcomes and Behavioral Evidence (PROBE)

Project Management Team funded by the Global Health Partnerships of the Pfizer Foundation and the King Baudouin Foundation



Administrative Support/

Voluntary basis only for Sheila Sanderson



Aims and outcomes for 2011

- **We aim to address a number of research questions and obtain greater knowledge of QOL for clinicians, patient groups, service providers and more about the issues of designing, conducting and analysing QOL clinical trials**
- **Provide free and sponsored major training courses for Fellows for several 2 day symposiums with Faculty and ESO**
- **Produce 15 ASCO abstracts and 15 peer reviewed papers in high impact journals over 4 years**

Research support : by Advisory Board with the evaluation panel interlink with project management team

Advisory Board

Joseph Schmucker-von Koch
Jolie Ringash Charlie Cleeland

Carolyn Gotay Henning Flechtner

Eva Greimel Madeleine King

Martin Taphoorn Bryce Reeve

Joachim Weis David Osoba

Evaluation panel

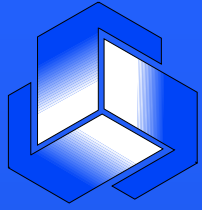
Kristin Bjordal

Michael Koller Jeff Sloan

Carol Moinpour



Bloomberg School of Public Health and GHP



Main ongoing analysis

- **Prognostic Factor Analysis**
- **Survival Analysis**
- **Longitudinal Analysis**
- **Cluster Analysis**



Members Area

password

Submit

Welcome to the EORTC PROBE Project

The EORTC Quality of Life Department has been established for over 15 years in one of the major cancer research organisations in Europe, the EORTC. The EORTC Quality of Life Department has recently been awarded a major grant to look at undertaking detailed analysis of clinical trial data, including offering training and fellowships over the coming years. The EORTC is in the fortunate position of having access to and generating high-quality data which is related to the psychosocial and HRQOL functioning of cancer patients across Europe. Our PROBE project aims to tap into this data and the clinical network and fundamentally, via various research avenues help lead to better patient care.

We hope the PROBE project will shed light on many critical topics as yet unclear resulting in a significant impact on future psychosocial care. Eventually, we trust the PROBE project will influence policy makers, healthcare providers and services.

PROBE is fortunate in not only having significant research funding, and the support of the EORTC Board, but is also supported by an international advisory board that has been established, and will collaborate with the project management team. Additionally, EORTC members have been invited to participate in order to provide a balance of multidisciplinary skills and experience in all major fields.

This research is supported by the Pfizer Foundation



Upcoming Events

Kick-off meeting
10-11 April, 2008

Program available



PROBE ADVISORY BOARD 2008

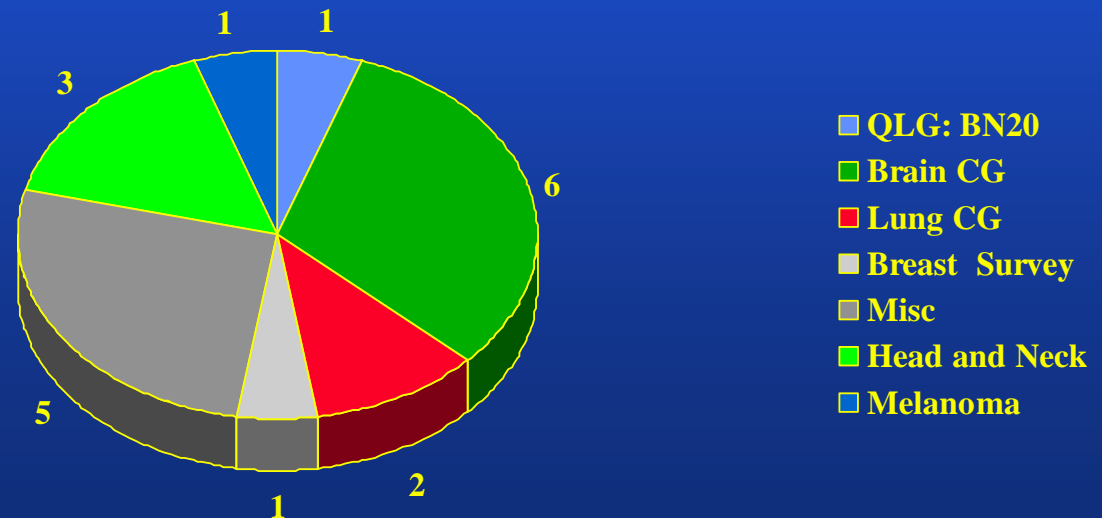


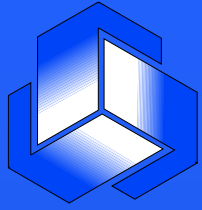
QLD scientific functions: New studies, analysis and preparation of trials and projects

* **New Studies** = 5 new RCT's with QOL in 2008 (including 4 registration/fully sponsored).

+

* **Existing studies** = Under pre-analysis/report preparation and discussion in 2008





Collaboration with the QLG

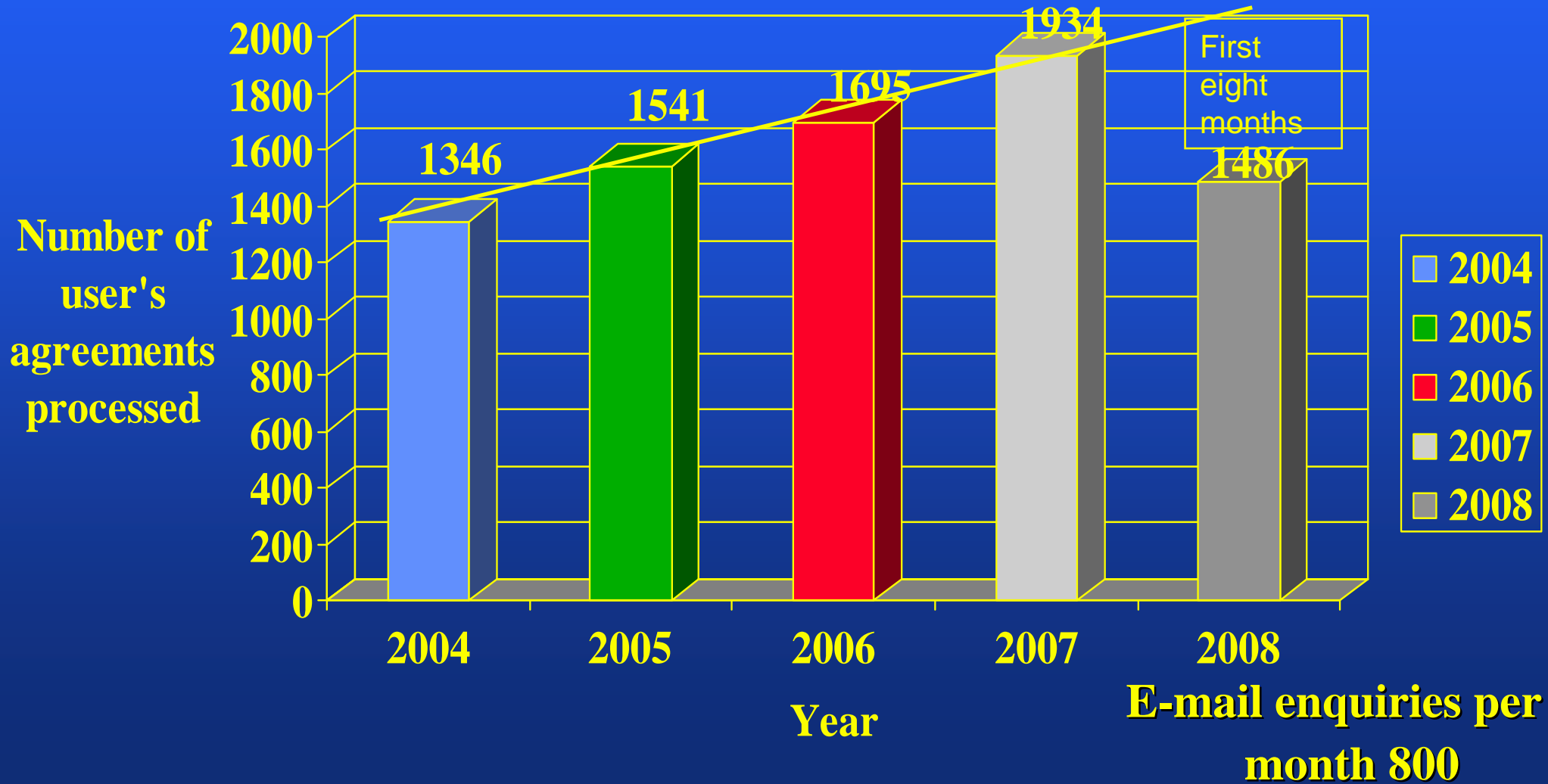
- Administrative and financial management (“front end” of the QLG business for over 15 Years). With QLD grants included, over 1 million Euros (contracts) per year pass through the Department
- Translations
- Management of requests from academia
- Website requests and central coordination
- Collaboration on Modules and Item Bank
- Ad-hoc analysis of selected modules (BN20, Info, Mets)
- Support for newsletter and other admin. tasks such as organisation of meetings.

Final HQ QLQ Validation analyses coordinated from the QLD

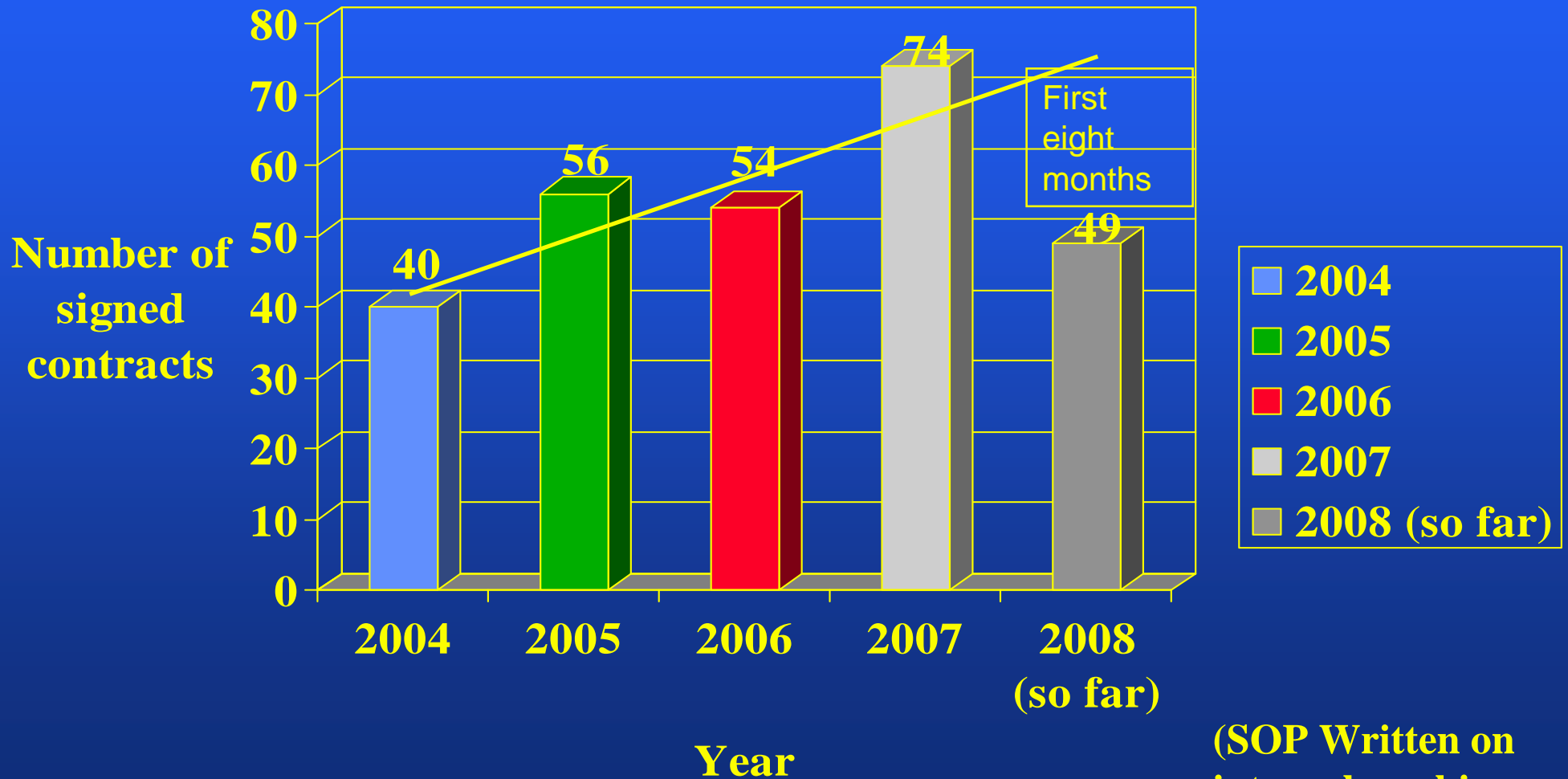
- **PR25 – in press with EJC**
- **BN20 – Draft report completed and draft paper being completed this month for EJC led by Martin Taphoorn**

QLQ-C30 + module administration

Total user's agreements processed

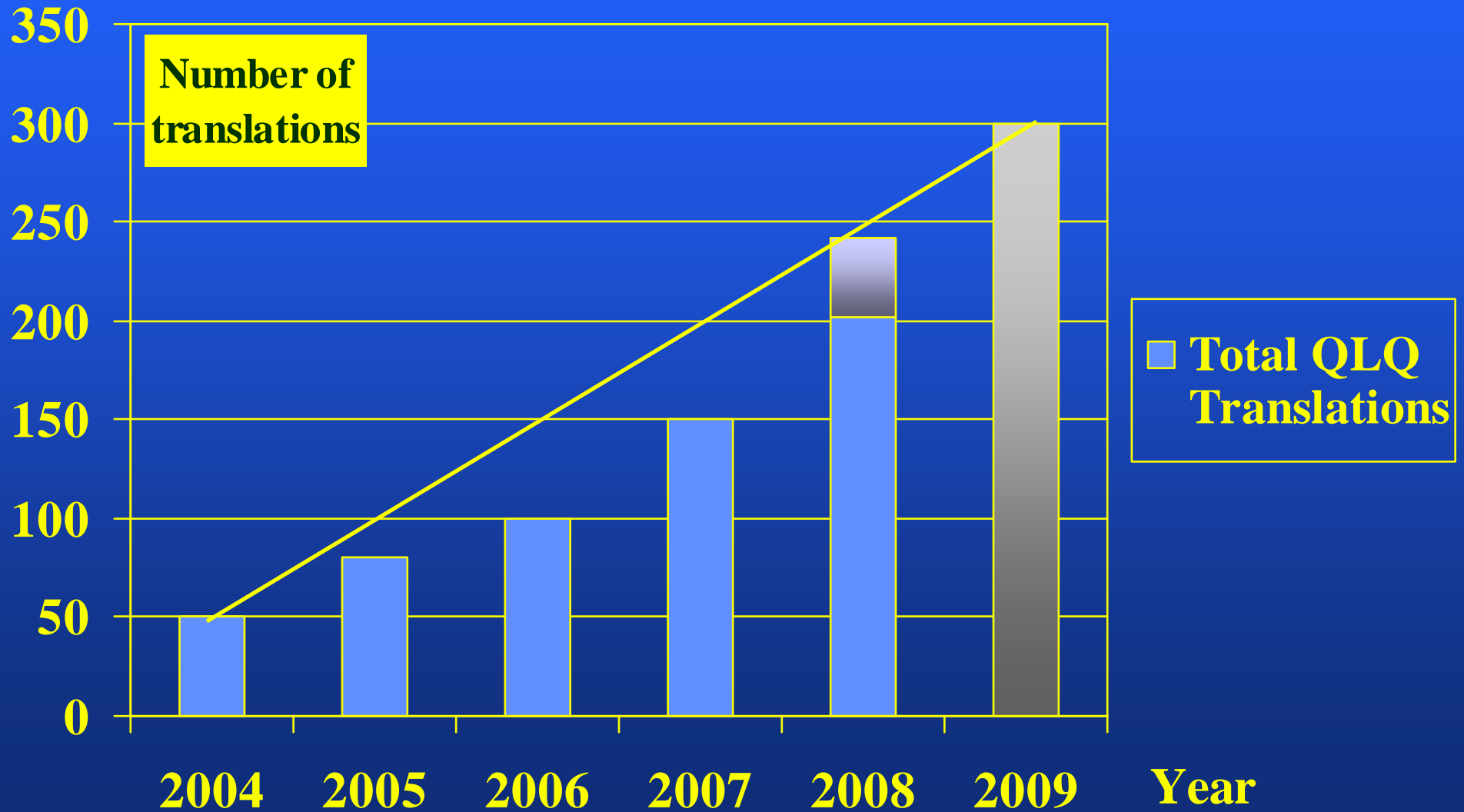


Contracts for commercial studies (for using the QLQ-C30)



(SOP Written on internal working procedures)

QLQ Translations Evolution



Translation programme

New staff: Petra Jeglíková (started on 11th August 2008 - **HALF TIME POST**)

Highlights:

- **202** translations coordinated in 2008 (**34%** increase compared to 2007):
 - 29 completed - 96 ongoing - 77 new - started
- Current overall status of translations: **776**
 - total validated (final stage) translations: 557
 - total n° of translations in progress: 219

Work in progress:

New validated translation updates are regularly announced on the translation section of the Quality of Life Group website:

New initiatives:

Translation Quality Assessment Process: ISOQOL Poster
Documentation, Archiving process

Revenue generated from new coordination fee will be “ring fenced” and used to provide staffing costs. New income already over €20,000

Production and distribution of QLG manuals, etc.

- **Annual Newsletters, Dr. Martin Taphoorn is the Editor. Local production is done by Sarah Williams, Sheila Sanderson, Andrew Bottomley with Brief Ink publishers in Brussels**
- **QOL CDs still being distributed at various meetings (eg: ASCO, ECCO, etc): Fundamentally used as promotional material**
- **Blue books/guidance manuals: All now pending updating, printing and distribution**
- **Translation Manual update near to completion and ready for circulation to co-authors**

Item Bank Version 2

- **Regular Meetings (last to date 16/7) status on the progress made and remaining issues**
- **Bug reports, bugs fixed, (but Linda has spent weeks solving this)**
- **“How-To” – Use the admin. interface (Administration guide)**
- **Final version expected to be finalised: 3Q 2008**
- **Once all bugs fixed QLG will make final payment for their data entry**

Summary

- **QLG collaboration with QL Department fundamentally administrative**
- **QL Department has a growing and diversified scientific workload**
- **QL Department scientific focus is on managing clinical trial design implementation, which is also becoming more labour intensive and with quicker response times expected**
- **New ideas for collaboration are always welcome, but funding and staff are also needed!**
- **Finally, don't forget the next QLG meeting is in Brussels with EGAM....**

**Come to Brussels,
EGAM
18 – 20th March 2009**

