



# Optimization of management of clinical research through the use of BI tools

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# Agenda



- Introduction
- About information needs in clinical research
- Cognos @ Astellas – small victories that made the change
- Lessons learned
- Next steps

# Who are Astellas

- Pharmaceutical Company
- Global Development
- European R&D with HQ in NL and Affiliates throughout Europe
- R&D Centres in Japan and USA



# Who am I, what is my role?

## Annet Rozema

- Joined Astellas in 1999 / various functions in R&D
- Current function (2007): Associate Dir. Business Intelligence / Report Program Mgr

## Current function:

- Position resides in R&D Business Information Management Department
- Global scope
- R&D BIM is part of Research & Development
- Internal advisory role

## Business knowledge is essential in my work:

- Understanding the business drivers
- Being aware about business processes
- What is the information need of the business
- Regulatory requirements

# About clinical development

## Clinical studies:

- **Early phase development:** many fast, simple studies, low numbers of patients
- **Late phase development:** longer run, fewer studies, more patients
- **Commercial studies:** big studies, often long duration (safety)

## Productivity / Costs:

- Only 10% of the compounds tested in humans reach the market
- Costs to get a new compound on the market: 1 billion Euro
- Development time: > 5 years after First in Human studies start



## Time is money

- Aim to rather terminate development project early; bigger trials are expensive
- Focus on time / try to be as fast as possible to gain time in making profit (patent expiry)
- Prevent overshoot in patient numbers (~20.000 euro per patient + delays)

# How are information needs in clinical development met?

- R&D Management information needs:
  - What studies are coming up?
  - Are studies on schedule?
- Study Managers information needs:
  - Manage large studies e.g. 20 countries, in 200 hospitals, including 3000 patients?
  - Insight in approvals, recruitment, issues
- Answer found in Cognos reports
  - Study Progress Report
  - Issue Report: issues are entered locally, monitored centrally
  - Standardization of study progress reporting
  - Easy to use solutions, pdf, scheduling



# Gradual growth of the Cognos system & use

## Started in 2006:

- Europe, 30 reports (re-built from legacy systems)
- Development of new reports, optimization of existing reports
- Adding data sources
- Increase in number of users, globalization of report usage

## Status in 2009:

- Cognos is **the global** Astellas R&D platform for mgmt information
- **One-stop-shop** for reporting in R&D
- Approximately 1000 users worldwide
- 80 Cognos reports
- Customized user portals (including pre-selection of reports, news)



# How to achieve increased acceptance & usage of reports @ Astellas



# Small victories in improved acceptance (1)

## 1. Department PDD

[1.1](#) Bar Chart PDD: Hours in current quarter (01-Jul-09 to 18-Sep-09)

[1.2](#) Table PDD: Hours in current quarter (01-Jul-09 to 18-Sep-09)

## 2. Section

### 2.1 PDD-CANDI

[2.1.1](#) Bar Chart PDD-CANDI: Hours in current quarter (01-Jul-09 to 18-Sep-09)

[2.1.2](#) Table PDD-CANDI: Hours in current quarter (01-Jul-09 to 18-Sep-09)

[2.1.3](#) Hour writing status PDD-CANDI: Target hours, written hours, approved hours

[2.1.4](#) Sick, Leave and non-Astellas time PDD-CANDI

[2.1.5](#) PDD-CANDI Hours per person, per network

### 2.2 PDD-CMC

[2.2.1](#) Bar Chart PDD-CMC: Hours in current quarter (01-Jul-09 to 18-Sep-09)

[2.2.2](#) Table PDD-CMC: Hours in current quarter (01-Jul-09 to 18-Sep-09)

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[2.2.5](#) PDD-CMC Hours per person, per

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# Small victories in improved acceptance (2)

## Scheduling of reports (pushing)

- Monthly list of changes in study planning

## Integrated Reporting

- Safety board receive report with data from two data sources (safety + study mgmt)

## Positive business case:

- Cognos licenses cheaper than read-only licenses to a system
- Security easier to implement with Cognos compared to source system
- Flexibility in the design was selling point

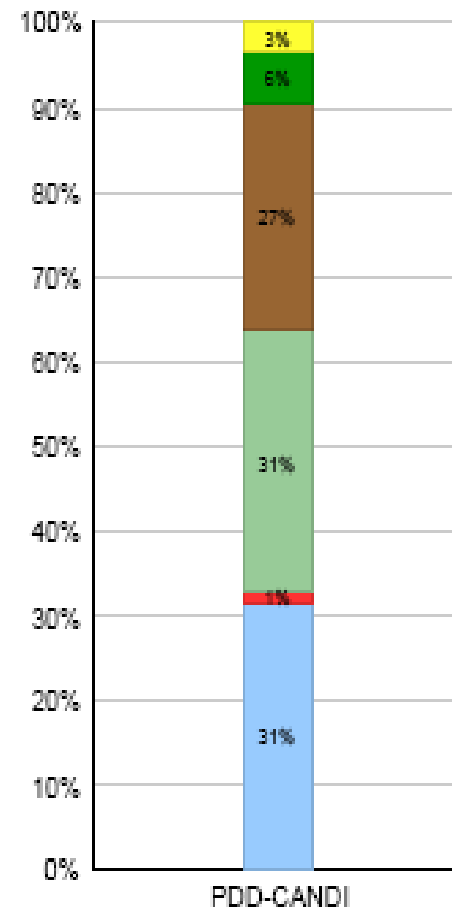
Wonderful

Wow!!

Very nice, thank you

# Small victories in improved acceptance (3)

- Offer alternative for SAP reporting (CATS)
- Quick results
- Understandable output
- Flexible selections
- Standardization of output
- Explanation of the content on cover page



# So....



- With a 5-fold number of users
- With a 3 fold number of reports
- With an explosion of additional report requirements
- With regulatory requirements that are tighter than ever

# The team has grown



# Lessons learned

- Be patient, usage will grow over time, but....
- Be interactive with the users
- Gain trust by providing high quality reports (close to 0 errors)
- Management buy-in is important, but bottom-up approach can also be quite effective
- Sell the story
- Surprise the users:
  - interactive approach during specification phase
  - advisory role
  - understanding the reason for report requests
  - approach the users instead of waiting for requests



# Focus in the upcoming period

## Report-related goals:

- Define & implement a governance model in place concerning reports
- Active maintenance of reports / phase out reports when possible

## Implementation of Data Warehouse

- ETL Tool / IBM Infosphere
  - IBM Business Glossary
  - IBM Datastage
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- Improved integration of data sources
  - Improving tools for monitoring data quality
  - Providing insight to users of data lineage