
The DataFax Platform at H.Lundbeck A/S: An example of successful technology integration

Gustav Sporon-Fiedler (IT Project Manager)
Marie-Laure Nowicki (Clinical Data Manager)

H.Lundbeck A/S, Copenhagen, Denmark



The DataFax Platform at H.Lundbeck A/S

- About H.Lundbeck A/S
- The H.Lundbeck A/S DataFax IT – Platform
- The End User Experience

H. Lundbeck A/S
Specialists in Psychiatry - Pioneers in Neurology

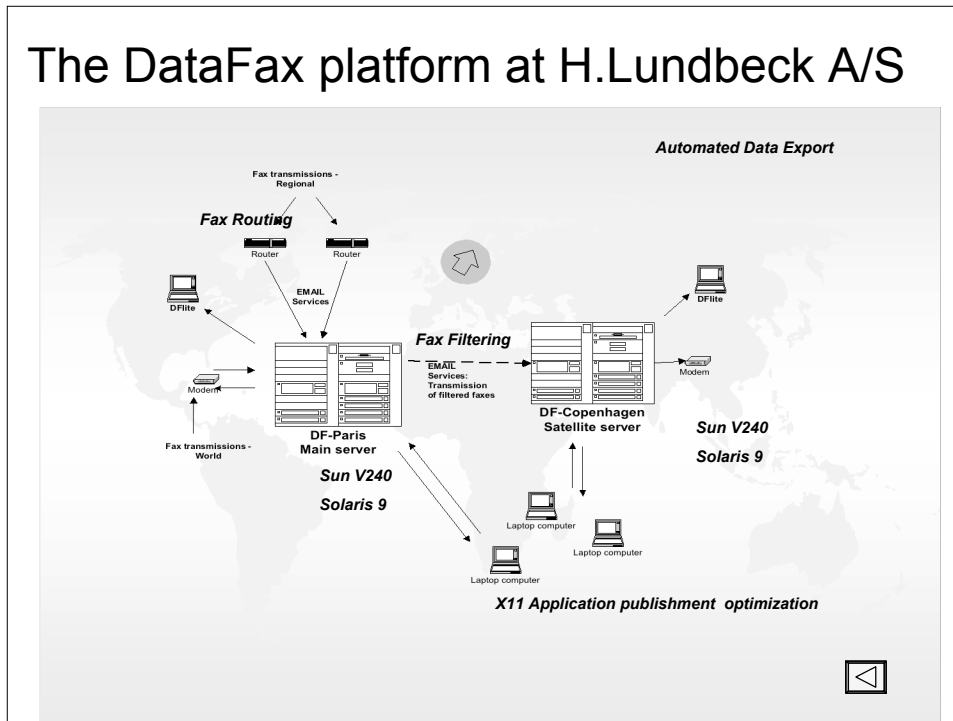


- **CNS Specialist Pharmaceutical Company**
 - Founded in 1915
- **HQ Copenhagen, Denmark**
 - Sales and Marketing / Partners Worldwide
- **Main Therapeutic Areas**
 - Depression, Schizophrenia, Alzheimer's Disease,
 - Parkinson's Disease, Insomnia

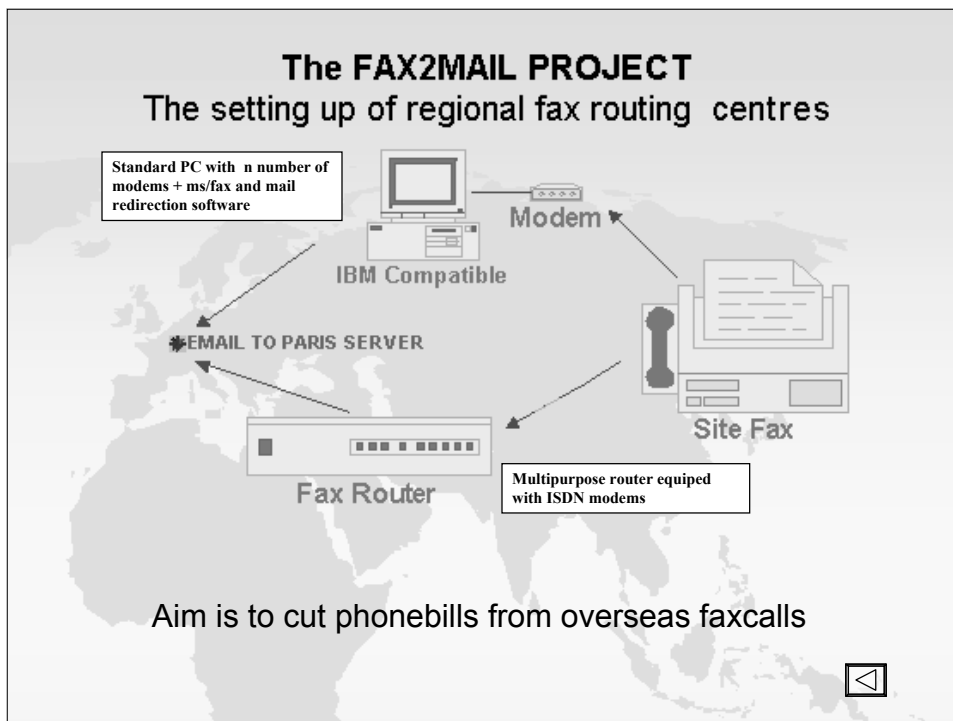
DataFax at H.Lundbeck A/S

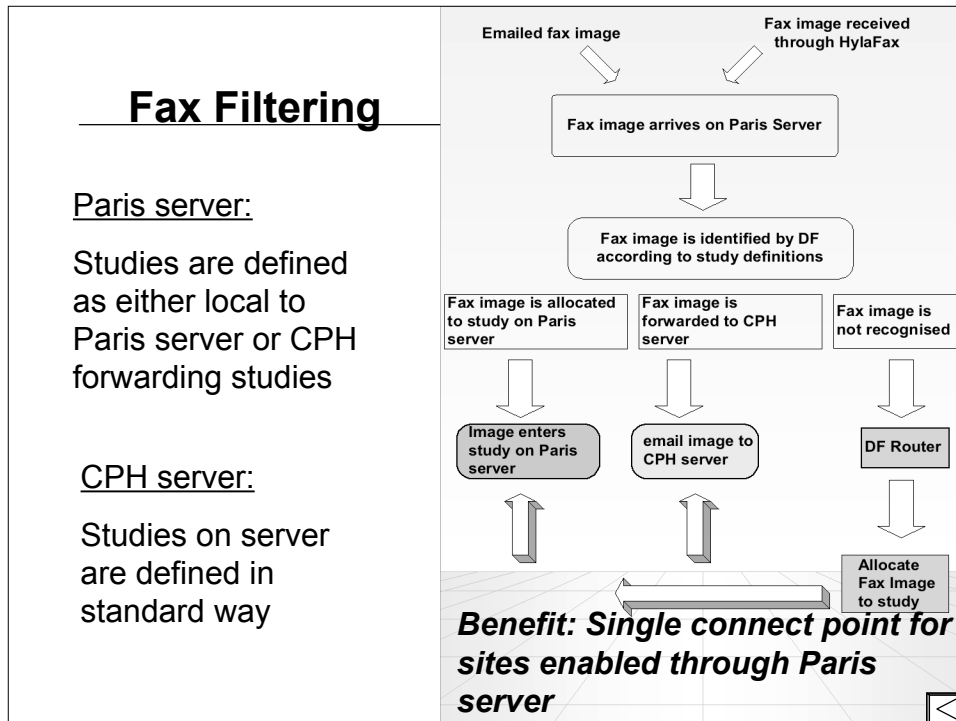
- 2002: First implementation of DataFax (Paris server)
 - ✓ Phase III/IV Pilot Study
 - ✓ About 10000 patients expected
 - ✓ More than 35 countries (Europe and Asia)
- 2005/2006: DataFax Setup of 2 new phase III studies and Implementation of the second DataFax server in Copenhagen
- 2006: 2 new Datafax studies, one setup on the Paris server and one on the CPH server
- 2007: One or more upcoming Datafax studies... :-)

The DataFax platform at H.Lundbeck A/S



The FAX2MAIL PROJECT The setting up of regional fax routing centres





X11 APPLICATION PUBLISHING Technologies

1. X-terminal emulator installed on PC client
2. X-terminal emulator installed on Citrix Metaframe server
3. Secure Global Desktop from Sun Microsystems

Three screenshots are shown on the right side of the slide. The top one is a 'Bceed' logo with a hummingbird and the text 'It's never too small to be big'. The middle one is a Citrix MetaFrame interface showing a login screen with fields for 'User Name' and 'Password', and a 'Log On' button. The bottom one is a 'Sun Secure Global Desktop' login screen with a 'Log On' button and the Sun logo.

End User Experience at H. Lundbeck A/S

End Users

System Support

DataFax IT
Project
Manager

DataFax
Administrator

EDC
Coordinator

Clinical Data Operations

Data Entry
Specialist

Clinical Data
Manager

Clinical Operations

Clinical
Project Team

Clinical
Research
Associate

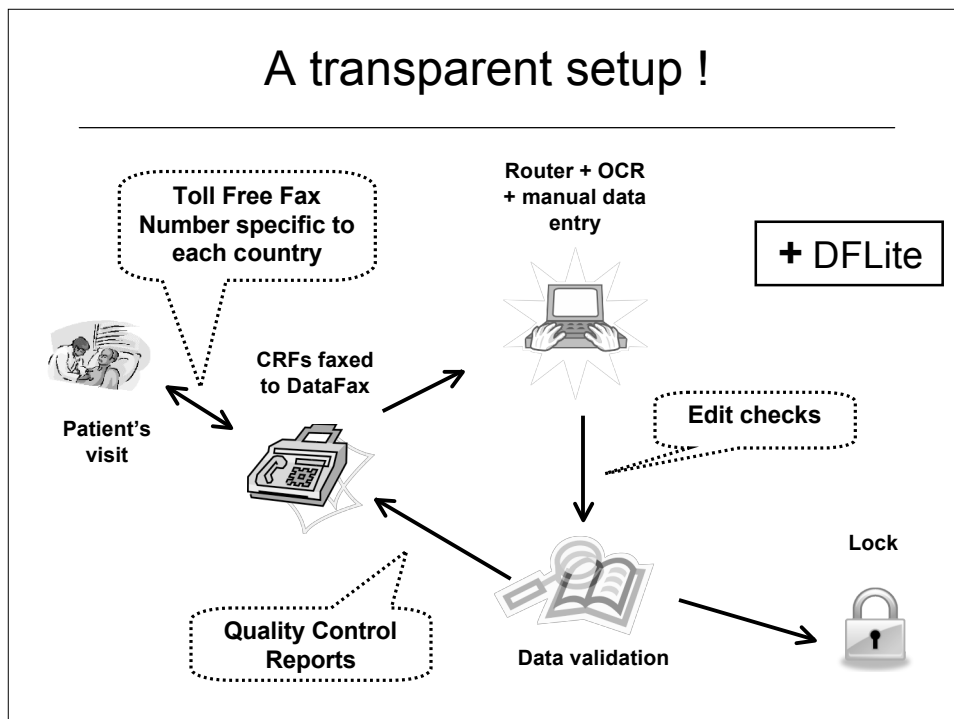
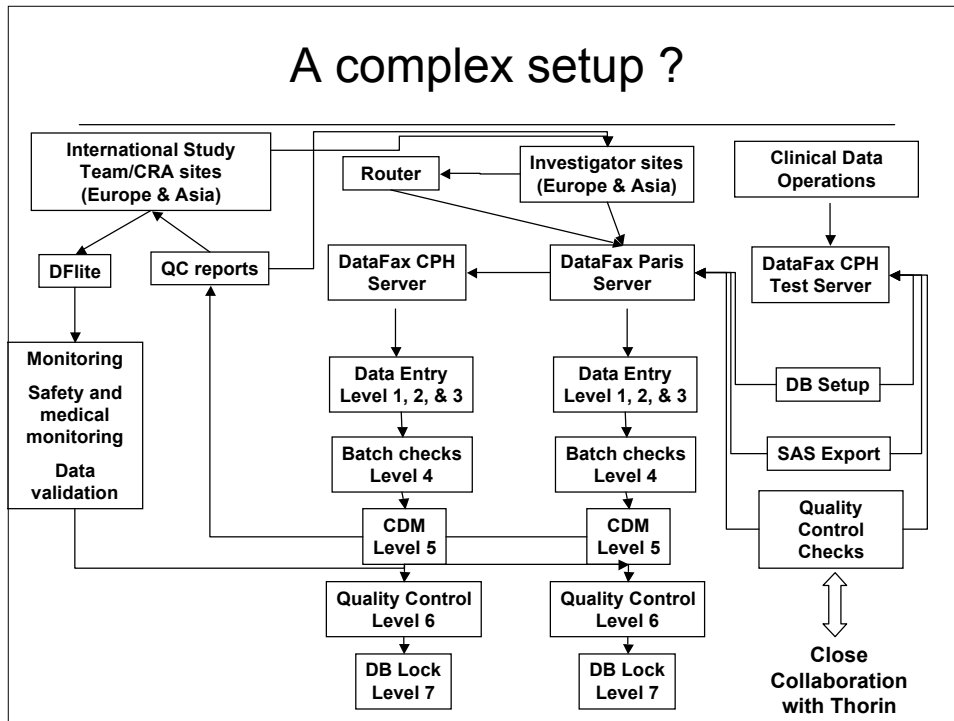
(Investigator)

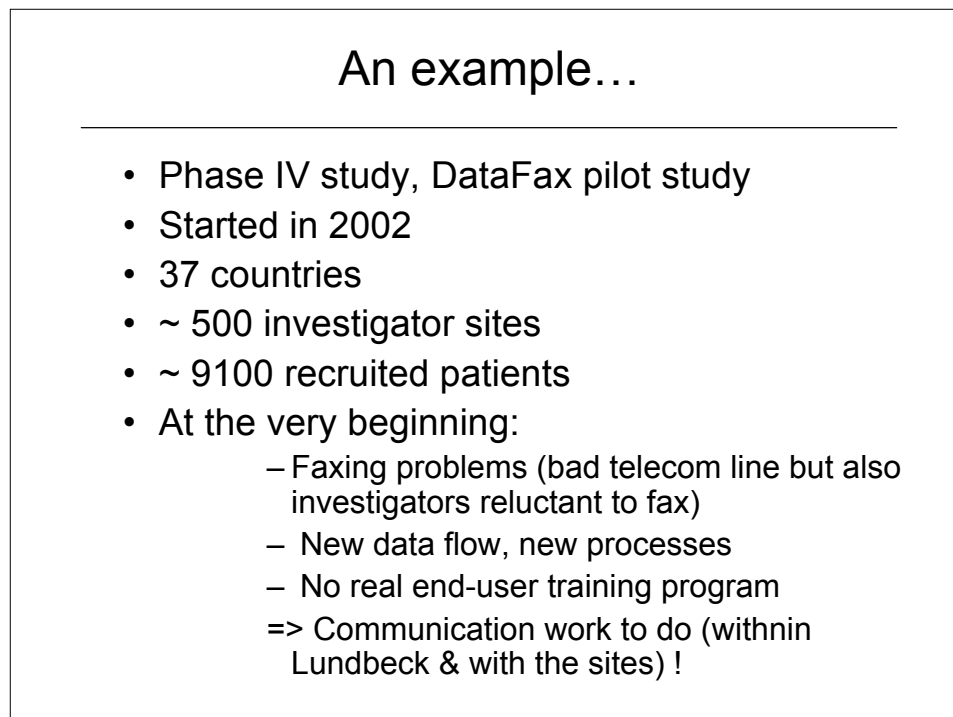
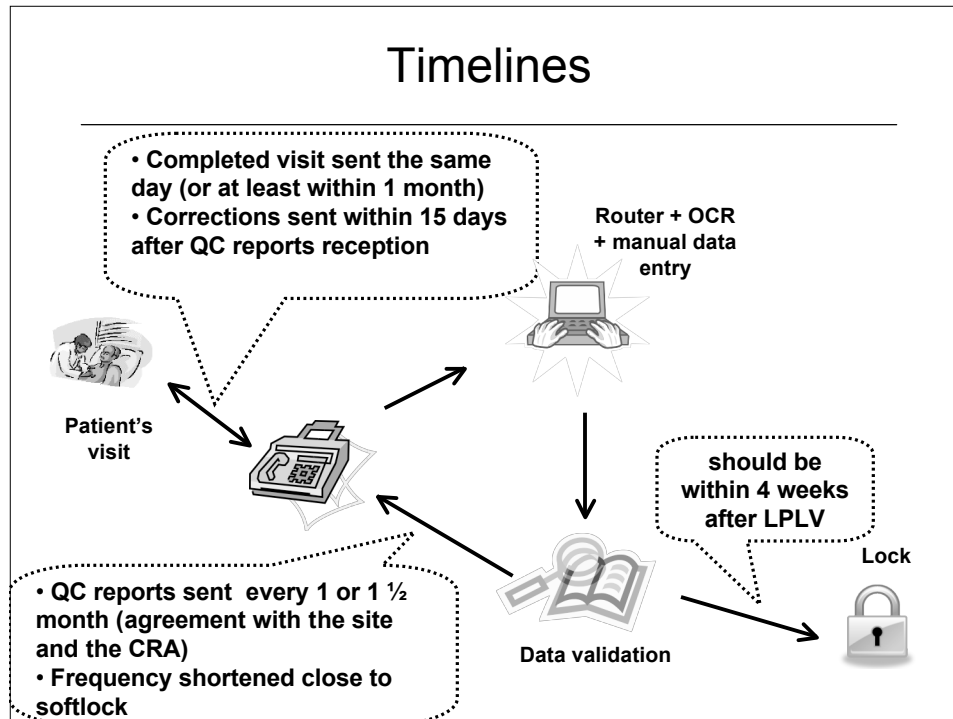
End Users Expectations (1/2)

- Clinical Data Operations
 - Quick reception of data to start cleaning early in the process
 - Easy identification of CRFs (automatic tracking of patients, easy access to queries...)
 - Speed and efficient query process to allow quick return of query answers
 - Early DB lock after LPLV (~ 4 weeks)
 - User friendly data management system (easy to use, quick time response, available reports...)

End Users Expectations (2/2)

- Clinical Operations
 - Early and direct access to the data at the patient level
 - Decreasing of the amount of query to the investigator
 - Short turn around time (early DB lock after LPLV)
 - Less monitoring visits
 - Removal of all logistic paper work





Today, are expectations met ?

- Quick reception of data
 - Speed and efficient query process
 - Quick return of query answers
 - Automatic CRFs/query Tracking
 - Report tool (only for CDM)
 - Early and direct access to the data at the patient level
 - Less monitoring visits
 - Removal of all logistic work
- ~20 days
 - ~10 days
 - ~15 days
 - Dflite
 - every 3 months

YES ! (new DataFax studies)

Still Some Issues...

- Still some faxing problems
The fax2mail solution is not available for all participating countries
- DataFax standard reports need some work around
They should be available and easy to use for the study teams (and not only the data manager)
- No database lock has been performed yet (ongoing studies)

THANK YOU !

Gustav Sporon-Fiedler (IT Project Manager) –
GSF@lundbeck.com

Marie-Laure Nowicki (Clinical Data Manager) –
MLNO @lundbeck.com