
The On-going Evolutionary Change of our Industry

Christian Mueller, PhD

Roche

In closing ... a tale of two companies and digital photography



Goodbye Kodak, Hello Fuji



[How **Fujifilm** survived: Sharper focus | The Economist](http://www.economist.com/.../2012/01/how-fujifilm-survive...)
www.economist.com/.../2012/01/how-fujifilm-survive...
Jan 19, 2012

- Kodak and Fujifilm both realized in the 1980s that photography would be going digital.
 - Both invested in digital technologies, and tried to diversify into new areas. Both had a wildly profitable film division that was late to admit that the film business was a lost cause.
- WHY ?**
- Today, Fujifilm is surviving while Kodak is not...
 - The big difference was execution.
 - (*Unlike Kodak*) Fujifilm realized it needed to develop in-house expertise in the new businesses.
 - The problem with .. (Kodak's) approach was that without in-house expertise, Kodak lacked some key skills: the ability to vet acquisition candidates well, to integrate the companies it had purchased and to negotiate profitable partnerships

Kodak was extremely innovative in its discovery and research

On October 15th 2010, President Obama named Steve Sasson as one of three recipients of the National Medal of Technology and Innovation for inventing the digital camera



Steven Sasson holds the prototype digital camera he built in 1975 at the Eastman Kodak Co. headquarters in Rochester, N.Y. It recorded a black-and-white image on a digital cassette tape. Photo: /Associated Press / AP

Many of Kodak's **key resources** and **capabilities** became virtually useless with this change:

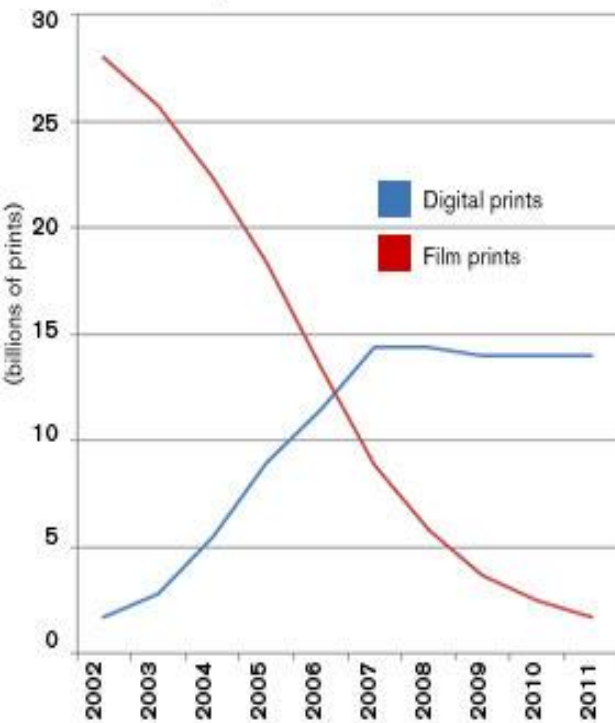
Roche



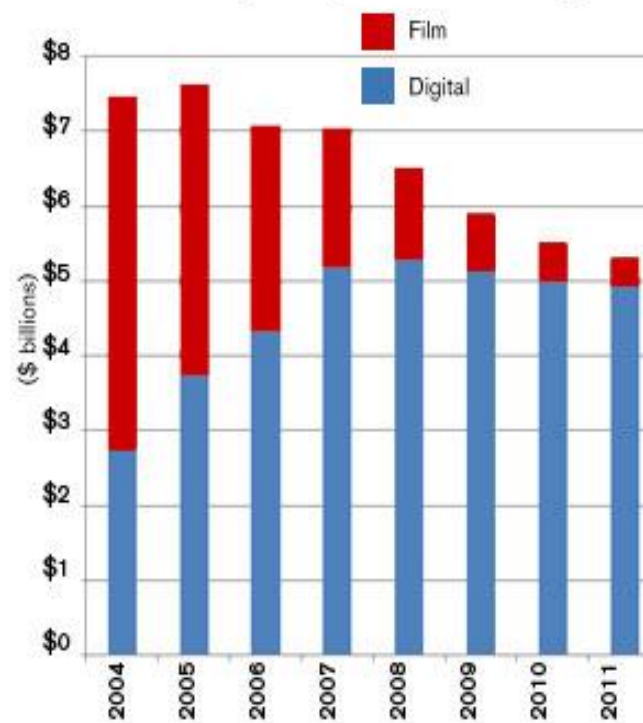
For KODAK, the external environment change came too fast.

Revenues Drop as Photo Printing Goes to Digital

Photo Prints by U.S. Consumers



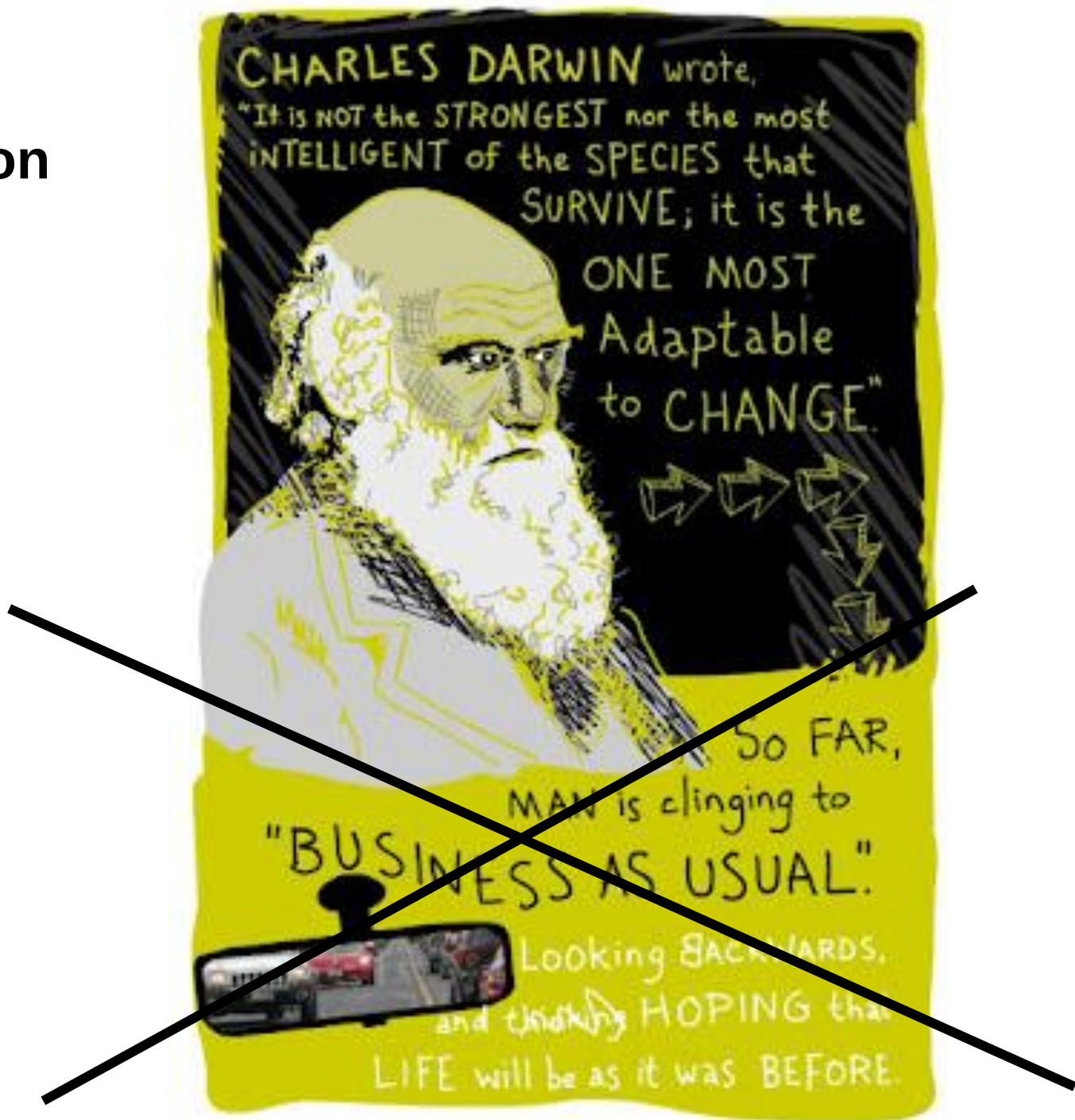
U.S. Consumer Spending on Photo Printing



Kodak's **resources**, its **capabilities** was destroyed, neighbours and around the event with their **recorders**, and upload to **flickr**...



The Lesson



Our view on how to sustain **2004**

What Does Success Look Like



Protocol adheres to standard convention

A screenshot of a web-based form titled "Study administrative record". It contains several input fields and checkboxes, including "Study administrative record", "Study administrative record", "Study administrative record", and "Study administrative record".

Standard eCRF panels selected

A screenshot of a data table with multiple columns and rows, likely representing a standard eCRF panel. The table has a header row and several data rows.

Selection of Standard Table & Listings Shells

A screenshot of a data table with multiple columns and rows, likely representing a standard eCRF panel. The table has a header row and several data rows.

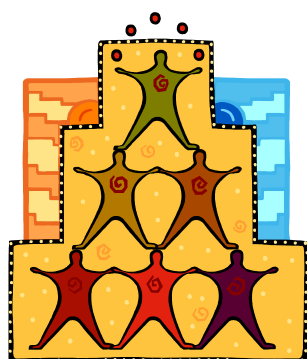
Selection of Standard Programs

Final Deliverables

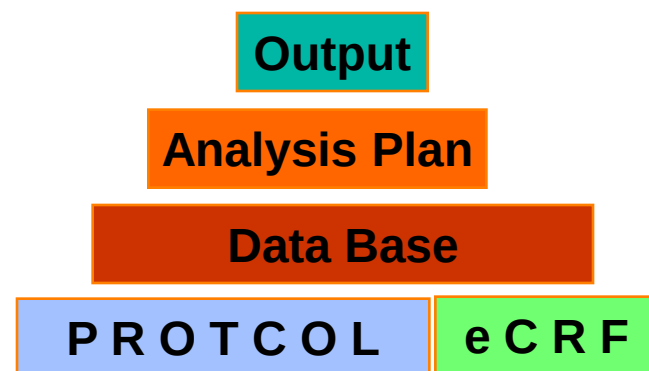
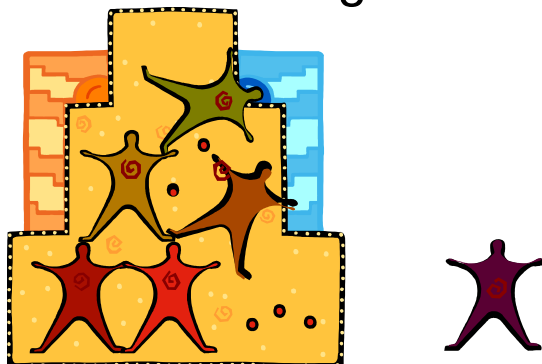
A screenshot of a data table with multiple columns and rows, likely representing a standard eCRF panel. The table has a header row and several data rows.

How Clinical Study Planning Affects the Standardization of Reporting

Adherence to agreed standards



Non-adherence to agreed standards



Specifications nuisance or core?
2008 -PHUSE

Terminology on specifications in this presentation

- For simplicity two main aspect shall be mentioned:
 - **User requirements specifications**: documentation based on a strong customer input, e.g. mock tables shells, general data handling conventions, derivations dependent on clinical input
 - **Programming specifications**: documentation with a focus on implementation by the programmers, e.g. analysis dataset specifications, additional information completing mock shells

Specifics in the clinical trial reporting process

- The quality of the reports is based on an **interaction between data and the code** processing it
- **All possible features of the data** are not known until shortly before final execution is needed (once all data is complete for a study)
- The overall work flow process of delivering **shortly after all data is available** (data base lock) requires that everything is planned, implemented, tested and reviewed by the customer sufficiently upfront.
- Drug Development is performed in a **scientific environment** which believes in the need to adapt based on new information

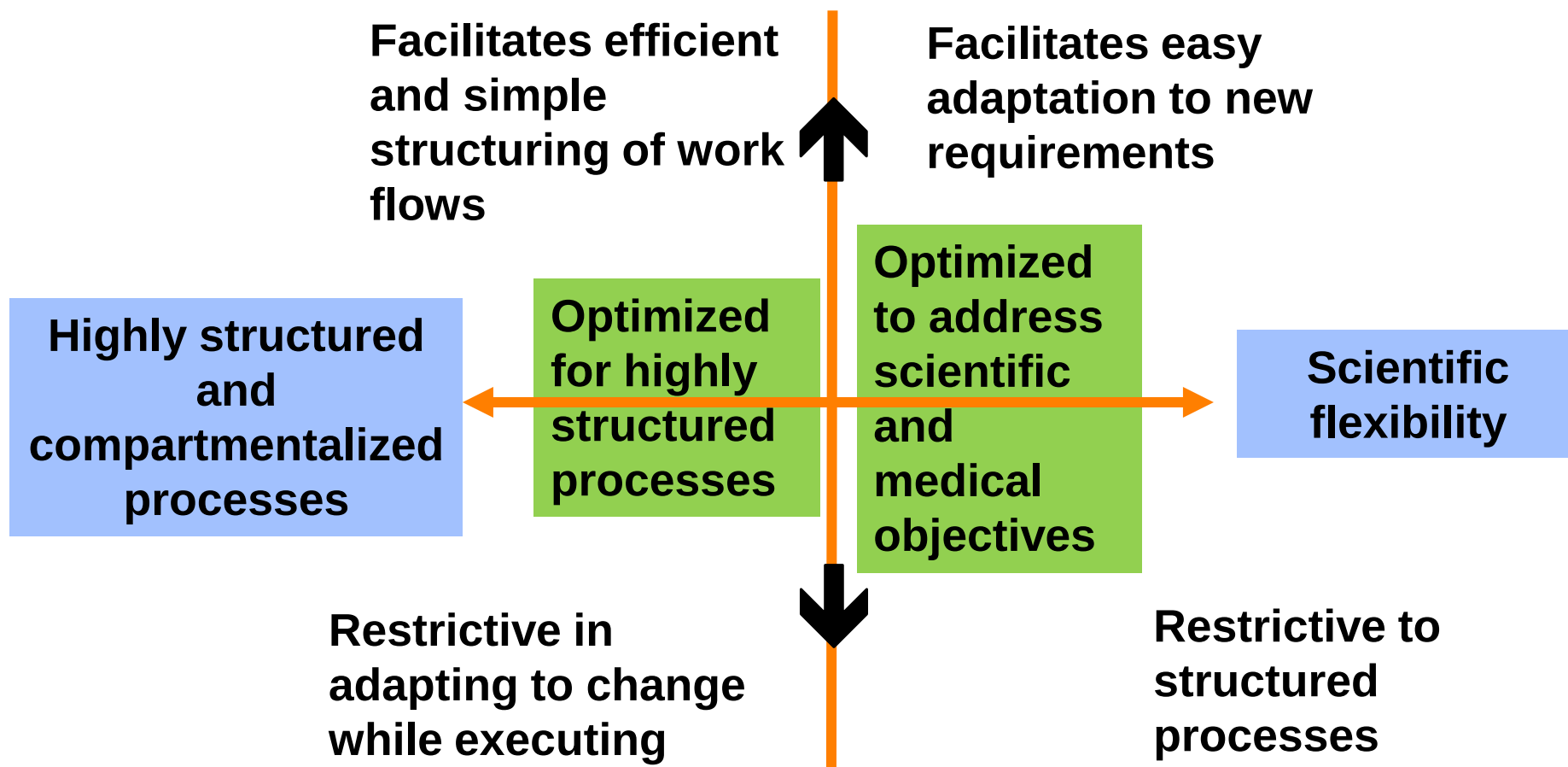
The customer

- Who is the customer **Statistics or is it Clinical Science?**
 - Both
 - Ultimately Clinical Science is the customer and play an important role in influencing the user requirements as well as changes and extensions to them.
- How close are we to Clinical Science?
 - Are we as close such that the goal of reporting clinical study data (text and data displays) is seen as **a joint effort**?
 - How often are we sitting down **together to discuss** about requirements and look at proposals?
- How well is the **understanding** of each others requirement and work processes?

... with a view on our environment

- User requirements and programming specifications are needed to perform testing/auditable quality control
- **But ...**
- How well does the **sequential focus** fit with a more **adaptive scientific** approach?
- How realistic is it that **all user requirements** for reporting an entire study are being **defined upfront** and documented before our work can actually start?
 - Theoretically it is possible
 - Practically it appears to break down more often than otherwise
- How **inclusive** is it for interaction between customers and programmers ?
- What are we **missing** in this approach?

My view 2008 - A Fundamental Paradox of Clinical Development

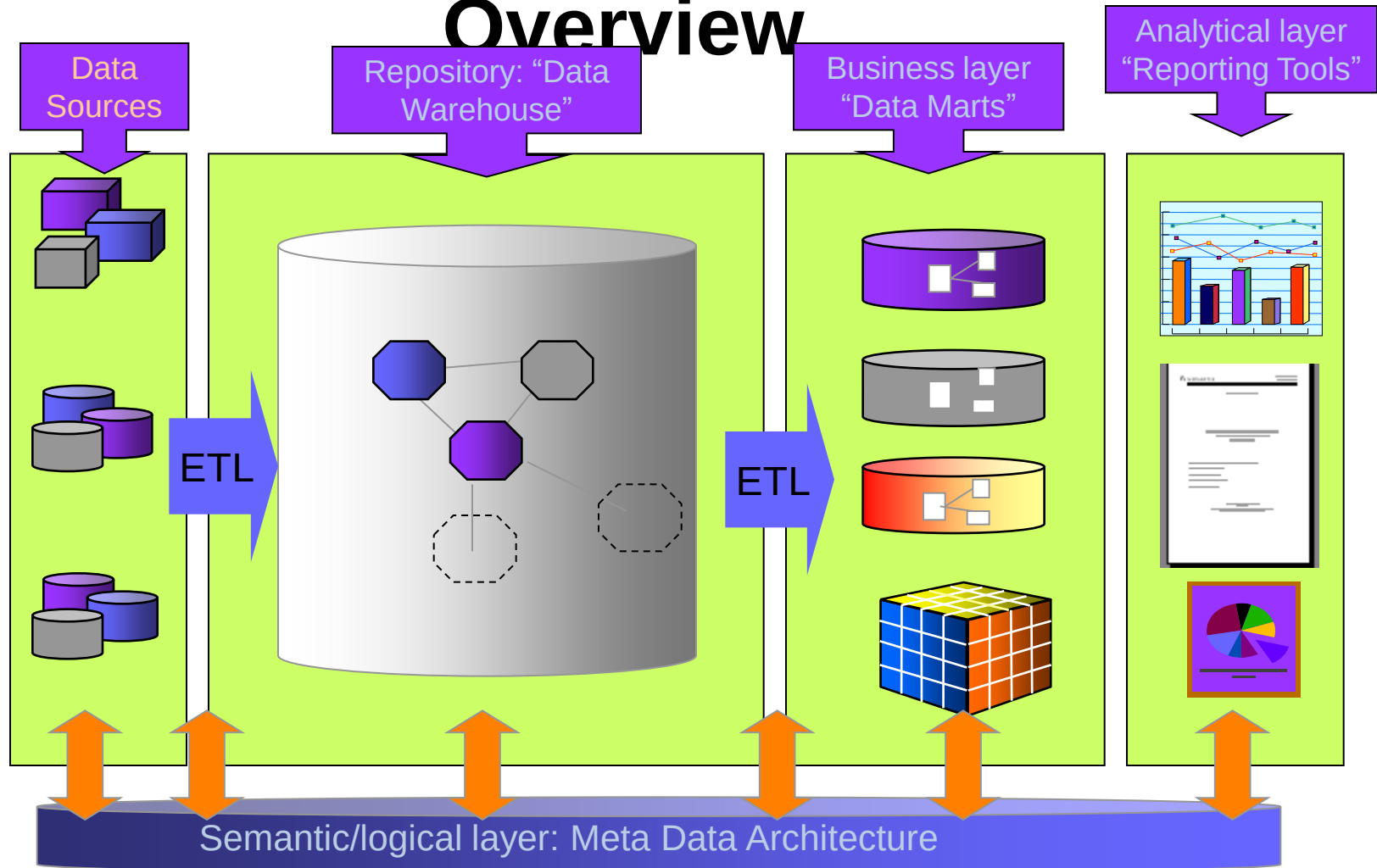


A Parallel evolution – presented at DIA 2007
Vienna

MAIN CHALLENGES AND POSSIBLE SOLUTIONS WHEN ESTABLISHING A CLINICAL DATA WAREHOUSE

Data Warehouse Architecture -

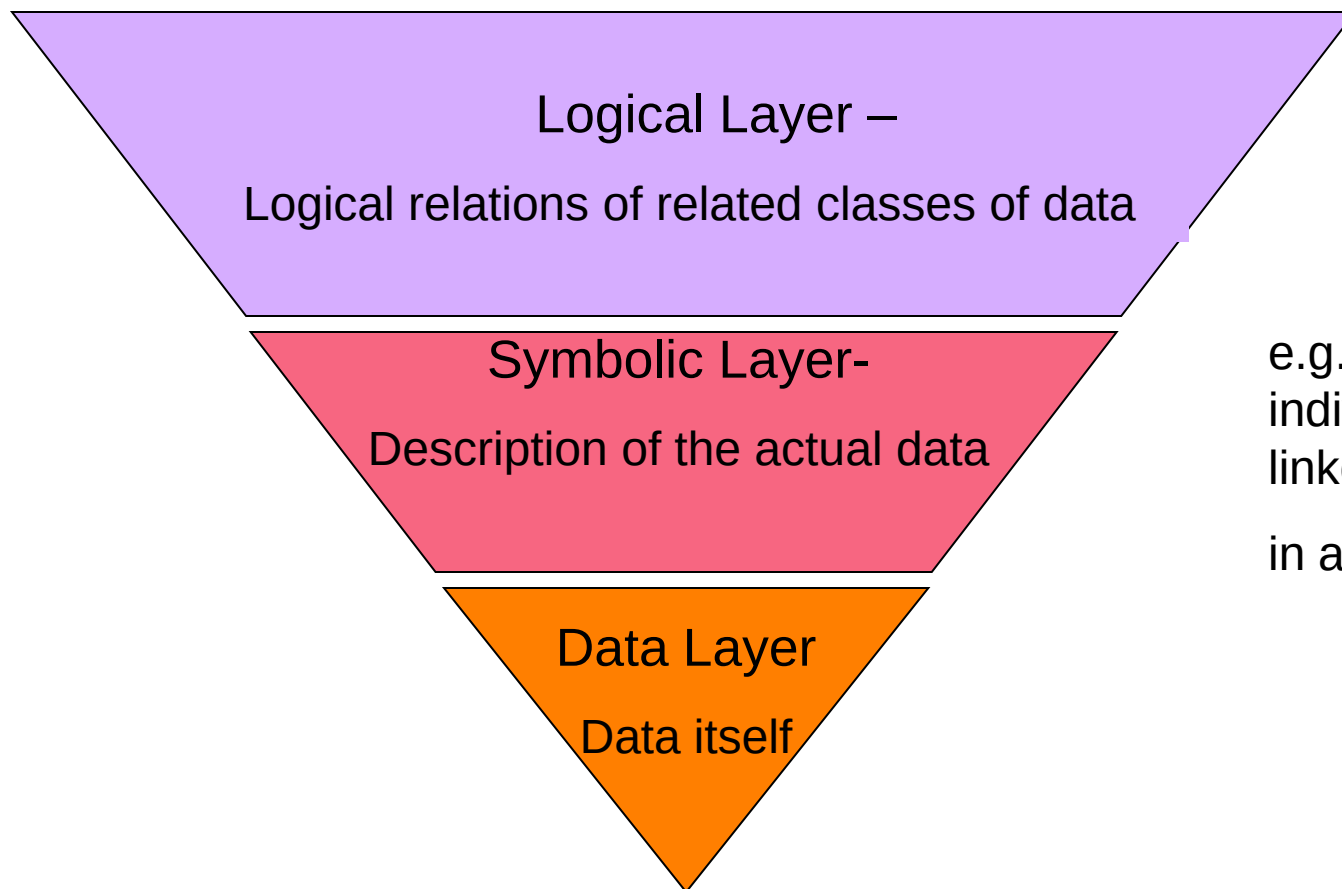
Overview



Managing Dynamics in Standards

- **Meta data driven** approach addressing the following requirements:
 - ◆ Definition of **logical relations** based on sequential modifications in the therapeutic area/corporate standard
 - ◆ **Hierarchical concept** based on relational comparisons:
therapeutic area/corporate standard $\subseteq$ project standard $\subseteq$ trial selection

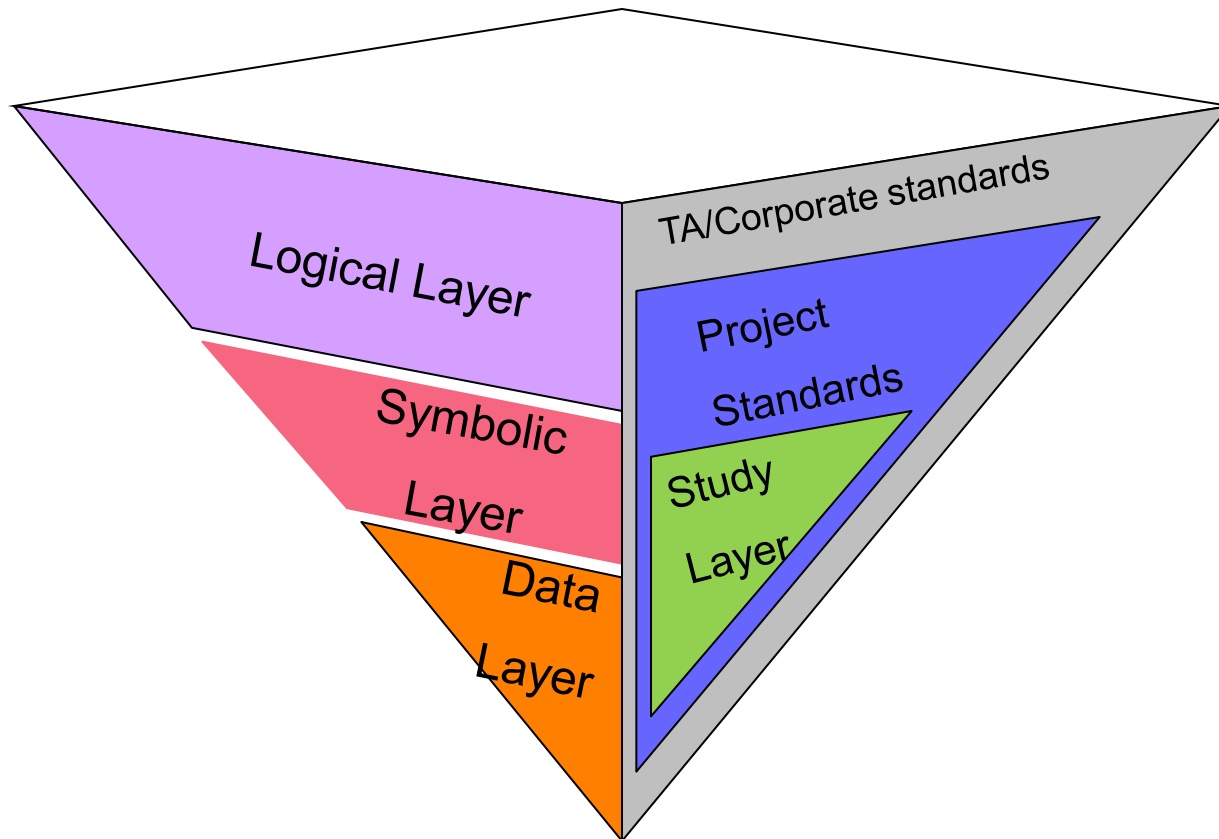
Meta Data Structured in a Hierarchical Arrangement



e.g. Mapping
rules between
possible code lists

e.g. attributes of data,
individual code list
linked to the data layer
in a study

The Second Dimension



- **“TA/Corporate standards”** provide the framework of options to choose from the symbolic layer and all corresponding information in the logical layer
- **“Project Standards”** define the sub-selection at the project level
- The **“study layer”** covers all physical data including the corresponding information from the symbolic layer

A story – PhUSE 2010 - Berlin

INNOVATION DRIVEN BY TECHNOLOGY

A nice story ... of success



Reservations take place by means of an entry on a reservation list, and the settlement on the basis of the logbook. The ignition keys of the cars are kept in a key box at the location, which the members can access with a master key.

Story continued



Along with a few mergers and reorganizations



Around PhUSE 2012 /2013

WHAT ELSE HAS EMERGED

In proportion to “google” hits

Crisis Management

Data Transparency

Data Visualization

Sourcing

Risk based Monitoring

Clinical Data Analyst

Big Data

Cost effectiveness

Search by term and Pharma

Questions and Opportunities

- What are we doing to related to new analysis methods – e.g. pattern detection?
- What implications will requirements for new skills and demand on data governance have?



What does it mean to be a Clinical Data Analyst



Responsibilities

- Close **collaboration** with stakeholders
- Define data quality expectations and understanding of the quality of available data
- Working in an iterative process
- Analysis and structuring of topical questions
- Presentations of results

Skills

- Good communication skills and collaboration
- **Understanding of data**, their characteristics and what is fit for purpose in terms of quality
- Agility
- Strong analytical skills, **Domain knowledge**
- **Presentation skills**

What does it mean to be a Clinical Data Analyst (cont.)



Responsibilities

- Preparing, **integrating data** from different source – handling of big data
-
- Analytical modeling to explore and **visualize data**

Skills

- **Strong programming** skills including high performance computing
-
- Knowledgeable at using **analytical software**

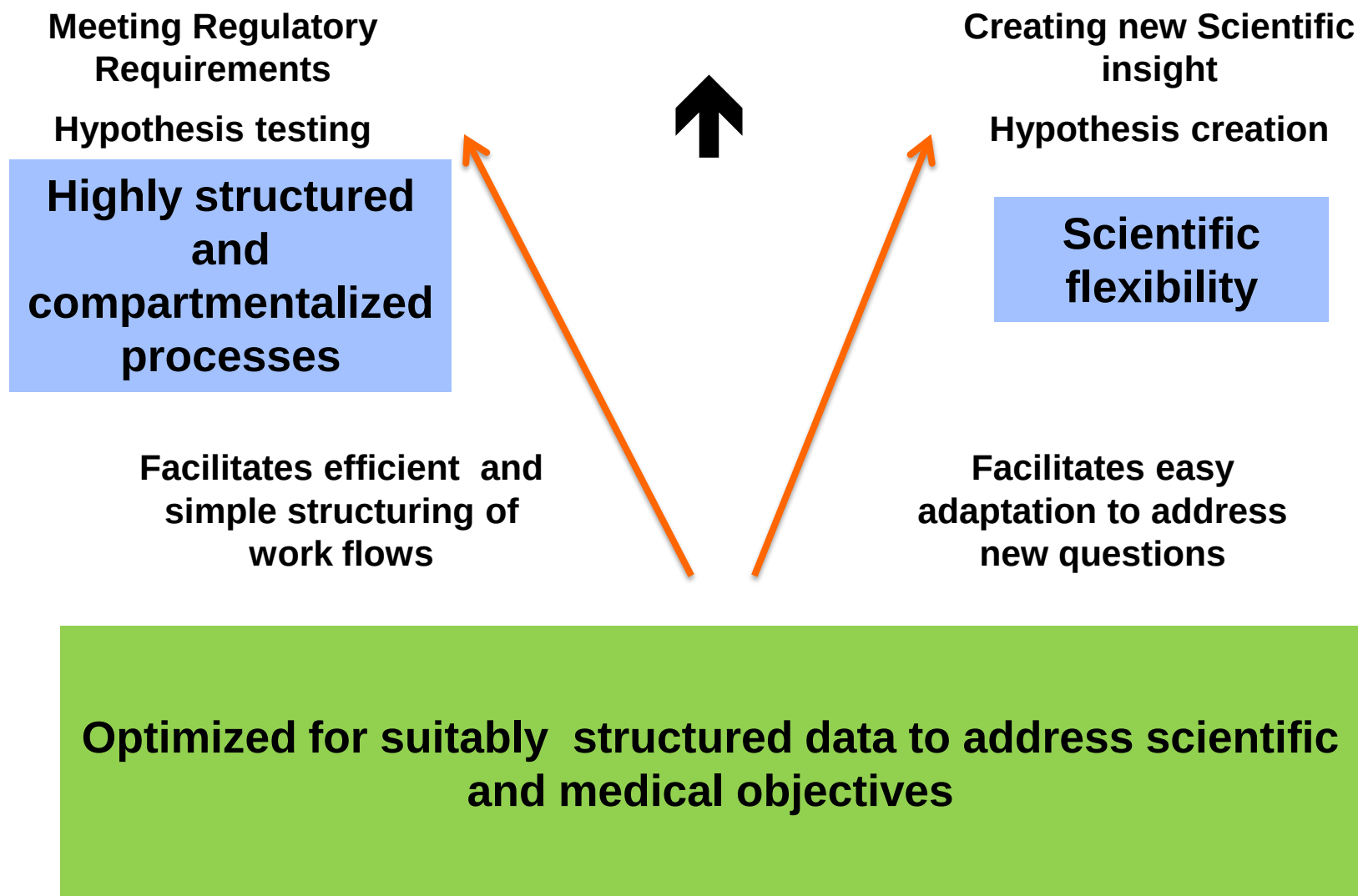
2014

HOW DID THIS EVOLUTION COME ABOUT?

Factors for a the emerging need of interactive analysis

- Everybody in the (Medical area) has a device that allows constant and instant access to data and information – **it is a common part of our live**
- **More and more data** is becoming available
- We have learned how to manage standards and integrating data – the implementation is going on
- More and more tools are emerging that allow interactive exploration and analysis of data also for
- Other Industry sectors are entering into the analytic space big time

A revised view 2014 – Resolving the Paradox of Clinical Development?



***Doing now what patients need
next***