



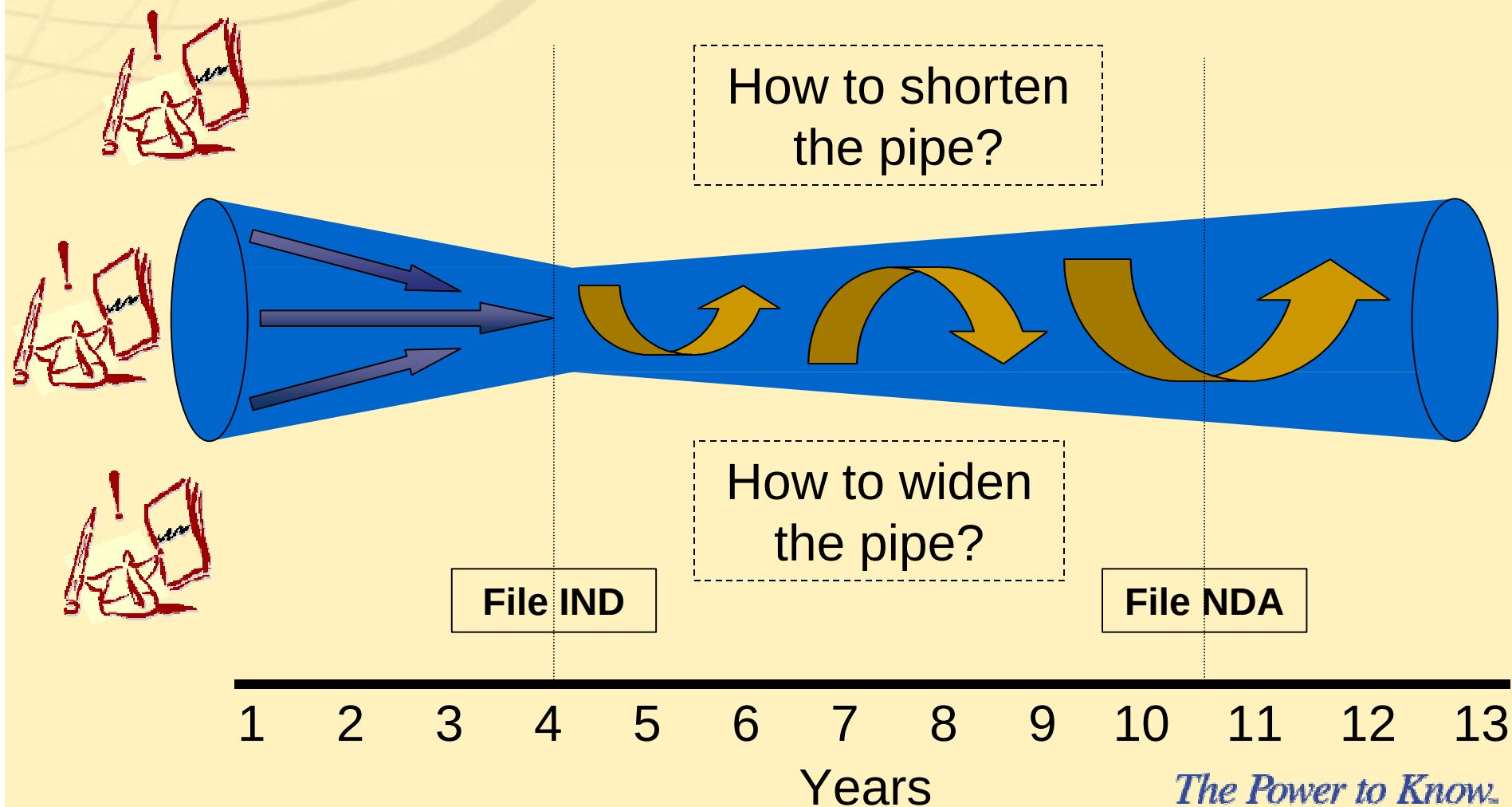
CDMKS

**Your Clinical Trials Data
Management System**

Jane Powell

The Power to Know.

Challenges in R & D: Drug Development Pipeline



Challenges within the Industry

- Reduce **Time to market**
- Increase profitability & **shareholder value**
- Perform **standardization and harmonization**
- Ensure **IT service levels** are being met
- Deliver product, process and service **quality improvements**
- **Comply** with regulatory requirements

SAS CDMKS - Brief History

Q1 2000

Consultancy Project undertaken to meet the specific needs of 1 customer :

- Phase IV marketing studies (therefore did not necessitate validated system)
- 2 specific studies
- No RDE
- New SAS site
- Rapid solution required
- Ease of use critical
- Version 6.12

SAS CDMKS - Brief History

Q2 2000

Project successfully implemented and accepted, on time and on budget:

- Customer expectations exceeded
- Site implementation and user training completed in < 3 days
- Ongoing support of < 0.5 day/month (largely due to changes in customer circumstances)

SAS CDMKS - Brief History

Q2 2000

- The success of this project resulted in extended awareness within the market place
- The UK Pharmaceutical team carried out a market research exercise
- *As a result it was decided to redesign the solution with increased functionality and using latest SAS technology*

SAS criteria to proceed

- Must meet the identified gap in the market
- Should not compete directly with key players
- Incremental Development of CDMKS:
 - » Release 1.0 to include core functionality,
 - » Additional functionality to follow
- Must exploit latest SAS technology

SAS Knowledge Solutions

Definition

- Package of Software, Knowledge and Consulting
- Answers single business problem
- A focused well-defined solution
- In a particular industry or functional area

SAS Knowledge Solutions

Clinical Data Management Knowledge Solution

The first knowledge solution to be developed in the UK

Key objectives:

- speed up Clinical trials
- increase the throughput of clinical trials
- provide a controlled environment for the data entry and data management of clinical trials data.

SAS Knowledge Solutions

Clinical Data Management Knowledge Solution comprises:

- Software - SAS Modules & Application,
- Consultancy - Installation,
- Knowledge Transfer - End users & administrators,
- Documentation - User guides & validation documentation.

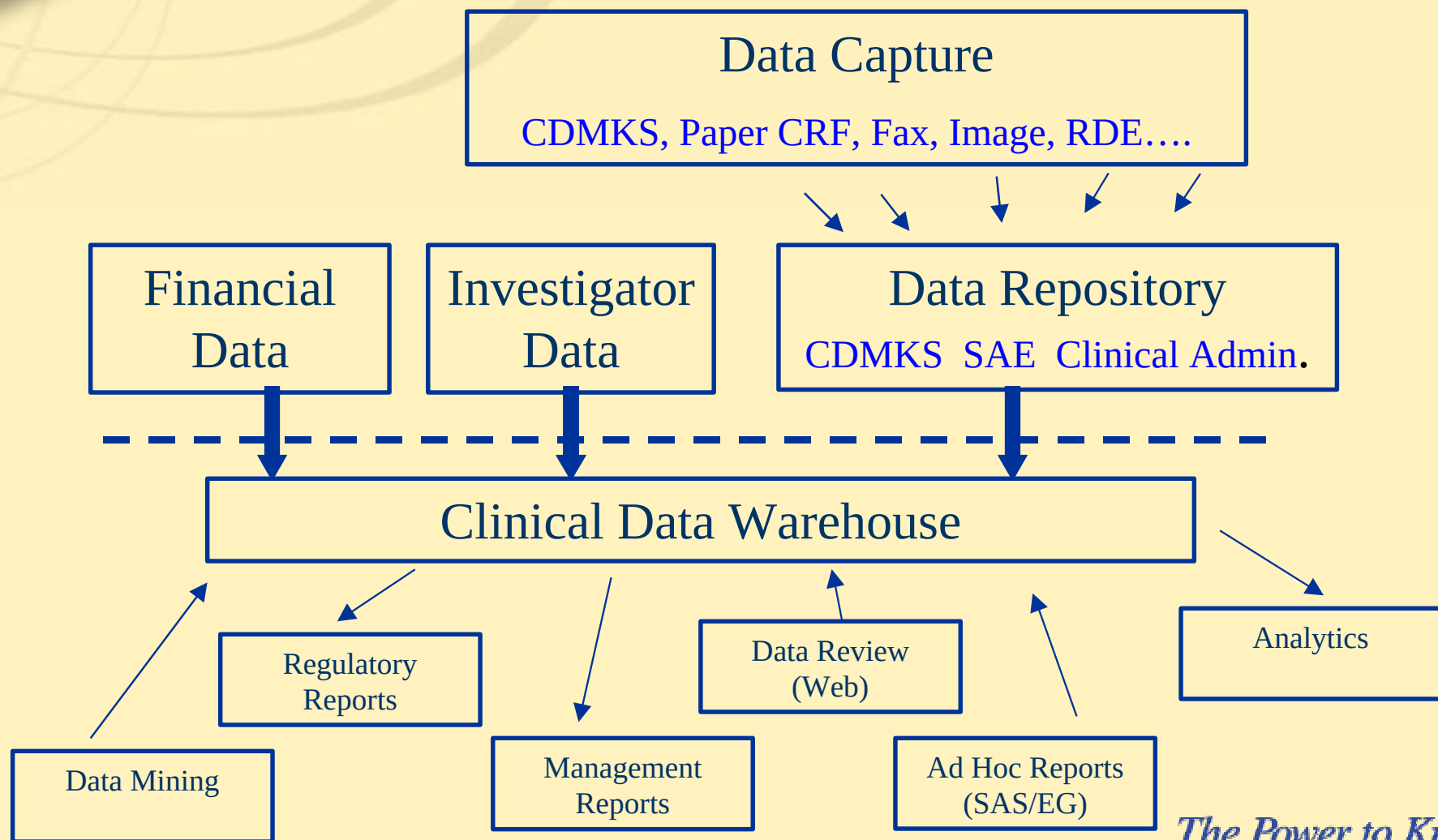
SAS Knowledge Solutions

Clinical Data Management Knowledge Solution primarily focused on:

- Phase I and IV Pharmaceutical trials,
- Animal Health trials
- Diagnostics and Devices trials

Suitable for all clinical trial phases

CDW & The Clinical Information Highway



Functionality

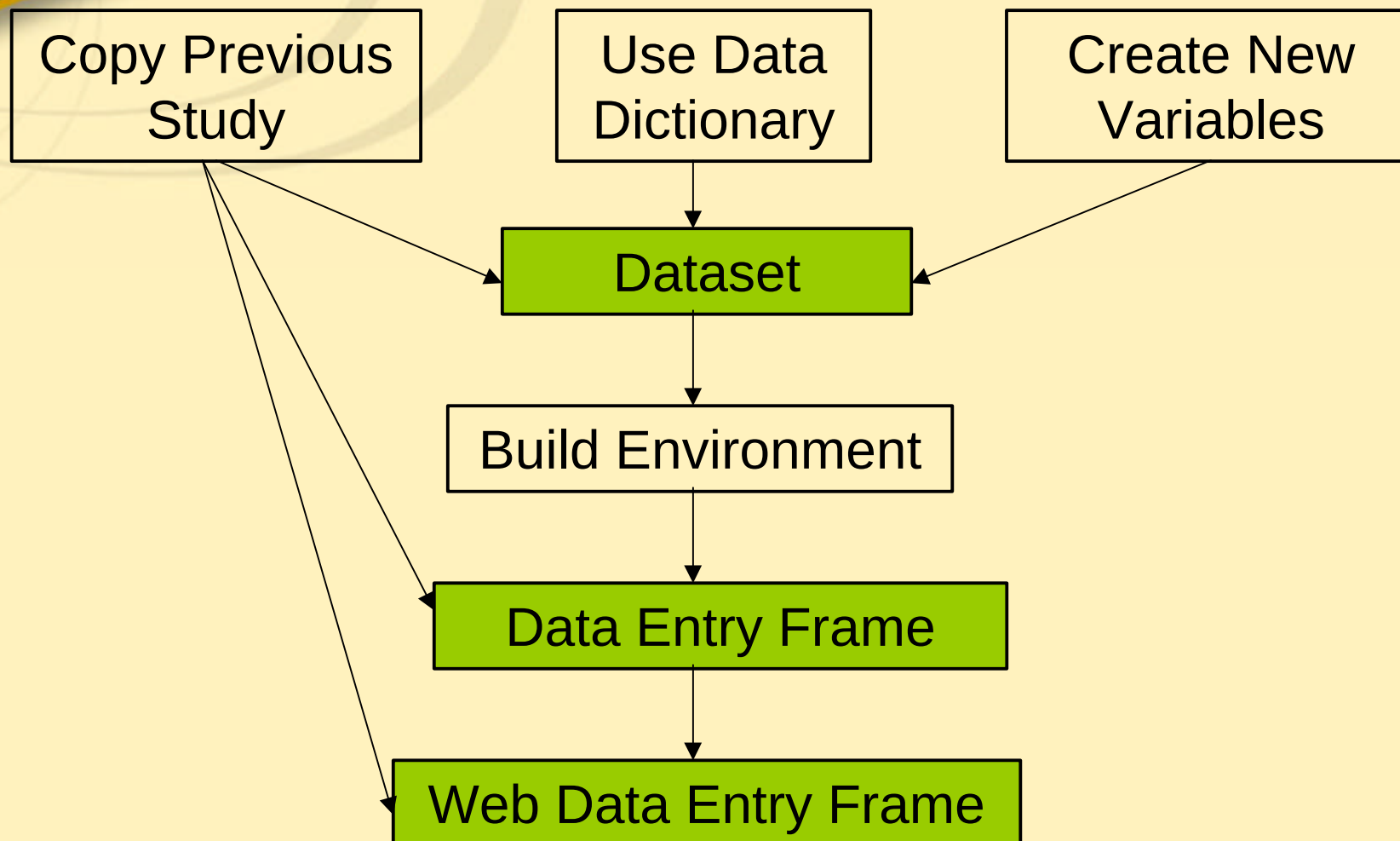
The Clinical Data Management Knowledge Solution is designed to:

- Enter, manage and deliver clinical trial data.

and is:

- Validated, flexible, portable, user friendly and quick to set-up.

Functionality: Study Definition



Functionality: Data Validation & Queries

At Data Entry

- Ranges
- Valid values
- Informats and Formats

Validation Manager

- Consistency checks using GUI interface
- More complicated checks programmed & stored

Query Manager

- Results assigned to targets e.g Investigator, CRA
- Linked to data for drilldown

Functionality: Reporting

Suite of standard metrics reports

- Adverse Events report
- Audit report
- Full data listing

User written reports may be added

Study data exported to other formats

- SAS datasets
- Excel
- CSV
- Access

Validation

FDA 21 CFR Part 11 compliant

System Validation Audit – PA Consulting

Quality System Development

Two Audits to Date

- Potential Client
- External ISO 9001

Status

Release 1.0 includes: data entry (local and/or web) and validation and query management

Subsequent Additional functionality to include:

- Lab loader
- Autoencoder
- SAE manager

Business Benefits

Requires minimal training

Users can be up and running
in a few hours.

Has rapid study set-up ability

Object orientated front end,
enables quick and easy
database build.

Is portable and flexible

Full SAS functionality & fully
integrated with all other
SAS products.

***GREATLY SIMPLIFIES AND STREAMLINES THE
PROCESS OF CLINICAL DATA MANAGEMENT***