PAREXEL
Clinically thinking

Clinical Logistics

Central and Local Laboratories Management

CDISC LAB Integration

European Clinical Logistics Center

Version 1

Items to present...

- Overview PAREXEL's Laboratory Services
- How do we work with CDISC Laboratory Standards?
- Short Overview about the "2 Lab standards" in CDISC
- PAREXEL Implementation feedback
- The Future…

Who we are...|

PAREXEL's

European Clinical Logistics Center

- located in Berlin, Germany
- operating unit within Clinical Operations (Monitoring).

Main task:

- coordinating and organizing the whole process
- from provision of diagnostic supply material
- up to the provision of clean lab data results for clinical data management and clients

in close cooperation PAREXEL's own Laboratories/Pharmacies and our Partners.

The Laboratory Network...|

PAREXEL's own Laboratories and partners in Europe

Austria, Germany, France, Romania

ROW ☺

South Africa, Australia

and

Client's own Laboratories in

Austria & UK

Laboratory Logistics Services...|

Courier Management →

Laboratory Management ⋯⋯

- Lab Manuals
- SUPPLY/LAB-KITs
- Request Forms
- Transport Control Forms

Transport control (Inv. -> LAB)
Result distribution to Investigator
Laboratory Data Management

PAREXEL

Investigators

Samples

Local Lab's Analytics **or** Central Lab Analytics **or** Client Lab Analytics

Has CDISC any influence?...|

- None of the Laboratories deliver data in CDISC LAB format or CDISC SDS/LB table format right now
- Two Clients have asked for CDISC SDS LB data

BUT!!!!!!!!!

- Do you speak like an native English Speaker?

CDISC LAB Format...|

FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRE-SENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST
Good Transmission Practice (GTP) Level							
Study Level							
Site Level							
Investigator Level							
Subject Level							
Visit Level							
Accession Level							
Record Type Level						This level required	
Base Specimen Level							
Base Test Level							
Base Result Level							

- 11 levels of data

- 93 variables to be filled per record

FIELD NAME	REQD	SAS VARIABLE NAME	DEFAULT REPRE-SENTATION	MAX LEN	DATA TYPE	EXPLANATION	SUGGESTED CODELIST
Study Level							
Study ID or Number	Yes	STUDYID	(none)	20	Text	The ID of the study.	(none)
Study Name	No	STUDNAM	(none)	200	Text	The name of the study.	(none)
Transmission Type	Yes	TRMTYP	(none)	1	Code	This indicates what type of transmission the data transmission is. There are two transmission types: C - Cumulative I - Incremental	(none)

CDISC SDS/LB Table Format...|

Approximately 40 variables focus on Clinical Data Management, Biostatistics and Reporting

2.2.3 The Findings Observation Class

Table 2.2.3: Findings — Topic and Qualifier Variables, One Record per Finding (--TESTCD)

Variable Name	Variable Label	Type	Description
	Topic Variable		
--TESTCD	Short Name of Measurement, Test or Examination	Char*	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: PLATELET, SYSBP, PR, EYEEXAM.
	Qualifier Variables		
--TEST	Name of Measurement, Test or Examination	Char*	Verbatim name, corresponding to the topic variable, of the test or examination used to obtain the measurement or finding. Examples: Platelet Count, Systolic Blood Pressure, PR Interval, Eye Examination.
--MODIFY	Modified Term	Char	If the value of --TEST is modified as part of a defined procedure, then the modified text is placed here.
--CAT	Category	Char*	Used to define a category of related records. Examples: HEMATOLOGY, URINALYSIS, CHEMISTRY, HAMILTON DEPRESSION SCALE, SF36.
--SCAT	Subcategory	Char*	Used to define a further categorization level for a group of related records. Example: DIFFERENTIAL.
--POS	Position of Subject During Observation	Char*	Position of the subject during a measurement or examination. Examples: SUPINE, STANDING, SITTING.
--BODSYS	Body System or Organ Class	Char*	Body System or Organ Class that is involved in an event or measurement from the standard hierarchy. Example: the Primary SOC in MedDRA.
--ORRES	Result or Finding in Original Units	Char	Result of the measurement or finding as originally received or collected.

How CDISC LAB & SDS/LB helped?...|

•We build up an Web-interface to an analytical LAB in Germany.

Basic functionality:

•Barcode Process for each lab sample implemented at PAREXEL & LAB

•Study Nurse still has to enter Patient ID on sample label

•Sample will be scanned at Analytical LAB, ID data will be captured

•Validation alerts will be tracked

•Analysis gets started

•Logistics Managers clean the ID data in the meantime on-line (if required before analysis)

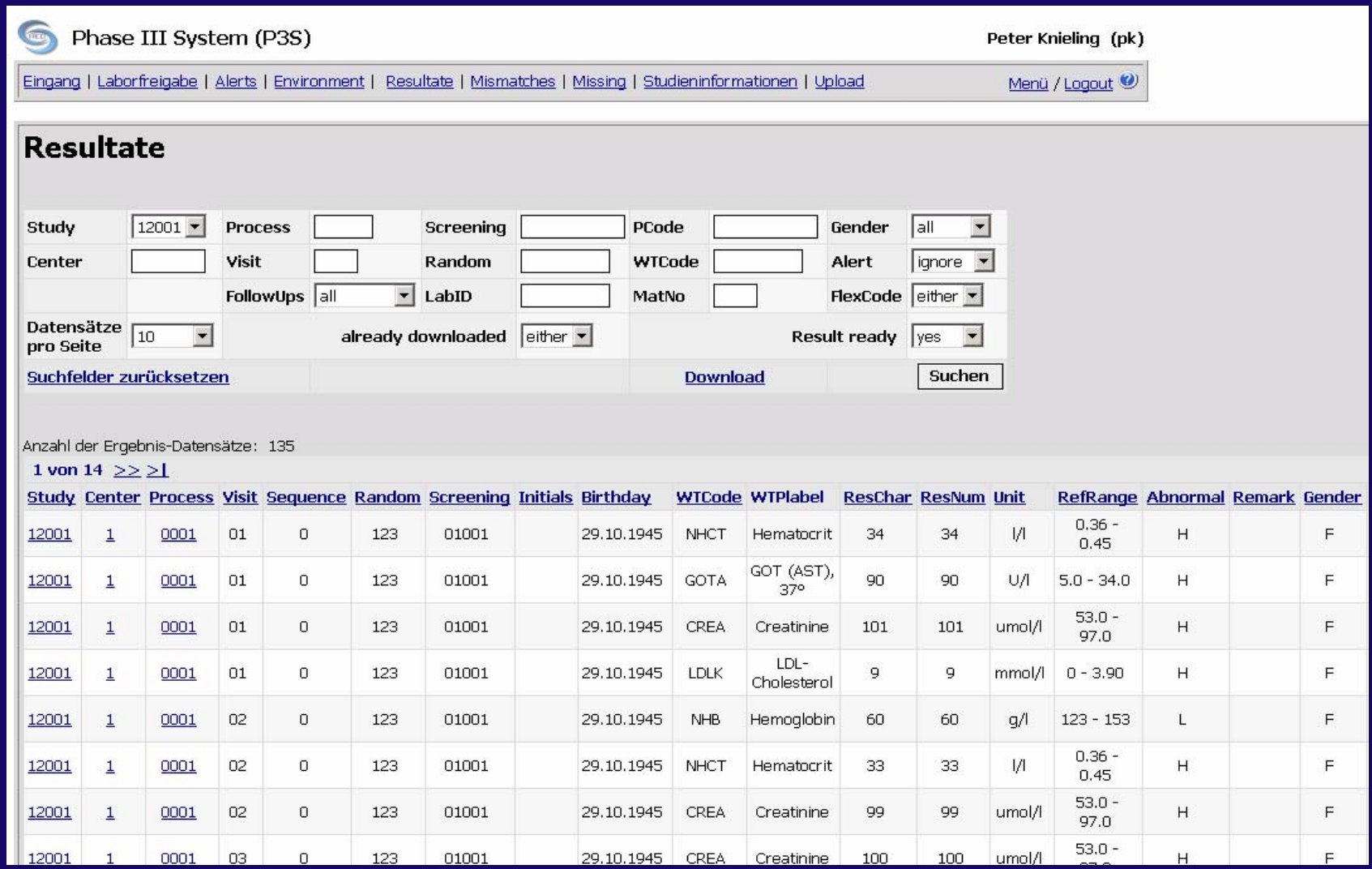
•Download of the data after analysis

•CDISC LAB format contains ca. 90 % of Variables for data exchange

•Perfect Basis for a System specification

•We finally split into a relational DB model for processing

How CDISC LAB & SDS/LB helped?...|



Phase III System (P3S)

Peter Knieling (pk)

Eingang | Laborfreigabe | Alerts | Environment | Resultate | Mismatches | Missing | Studieninformationen | Upload

Menü / Logout

Resultate

Study	12001	Process		Screening		PCode		Gender	all
Center		Visit		Random		WTCode		Alert	ignore
		FollowUps	all	LabID		MatNo		FlexCode	either
Datensätze pro Seite	10	already downloaded	either			Result ready	yes		

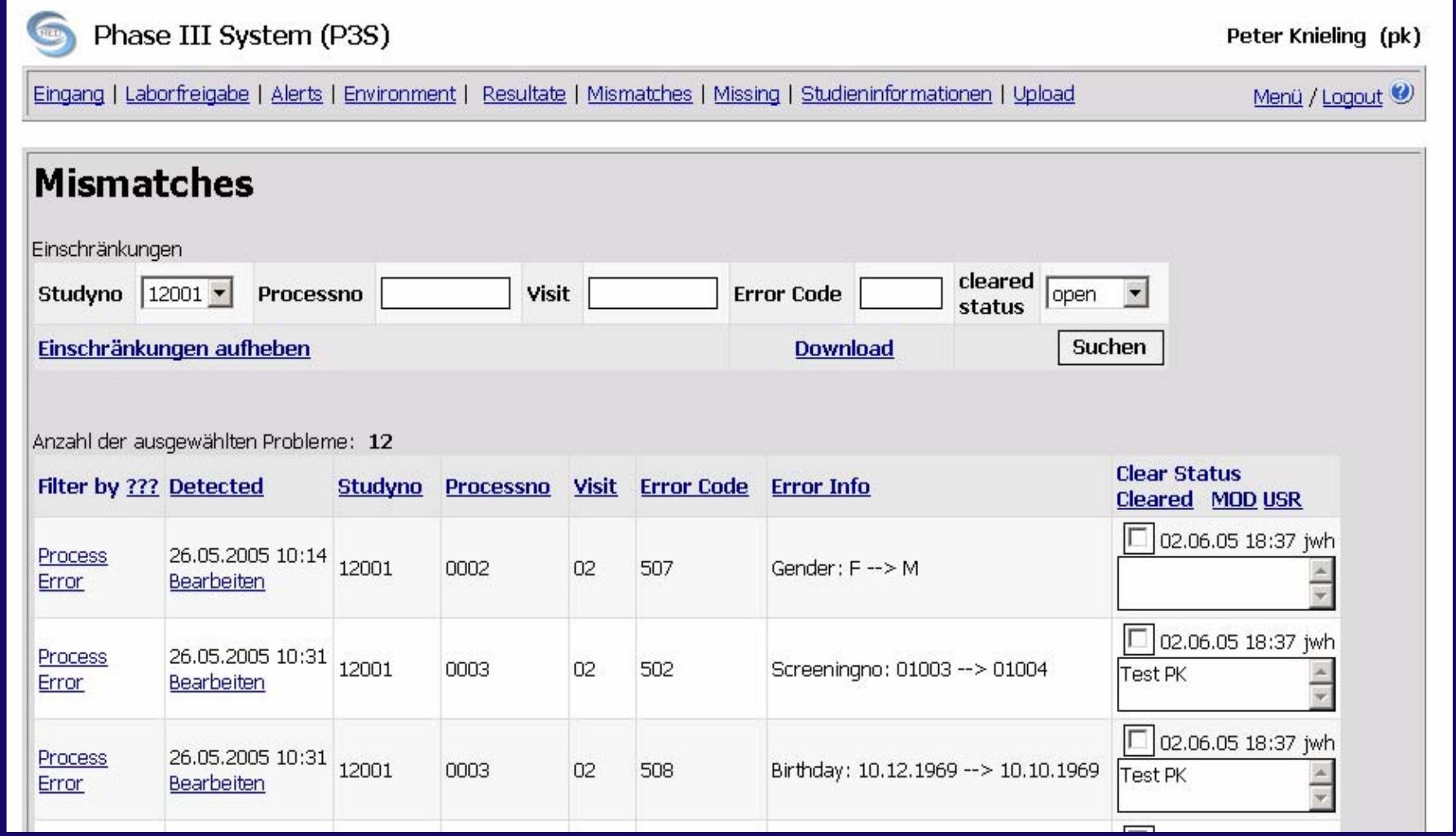
Suchfelder zurücksetzen | Download | Suchen

Anzahl der Ergebnis-Datensätze: 135

1 von 14 >> >|

Study	Center	Process	Visit	Sequence	Random	Screening	Initials	Birthday	WTCode	WTPlabel	ResChar	ResNum	Unit	RefRange	Abnormal	Remark	Gender
12001	1	0001	01	0	123	01001		29.10.1945	NHCT	Hematocrit	34	34	l/l	0.36 - 0.45	H		F
12001	1	0001	01	0	123	01001		29.10.1945	GOTA	GOT (AST), 37°	90	90	U/l	5.0 - 34.0	H		F
12001	1	0001	01	0	123	01001		29.10.1945	CREA	Creatinine	101	101	umol/l	53.0 - 97.0	H		F
12001	1	0001	01	0	123	01001		29.10.1945	LDLK	LDL-Cholesterol	9	9	mmol/l	0 - 3.90	H		F
12001	1	0001	02	0	123	01001		29.10.1945	NHB	Hemoglobin	60	60	g/l	123 - 153	L		F
12001	1	0001	02	0	123	01001		29.10.1945	NHCT	Hematocrit	33	33	l/l	0.36 - 0.45	H		F
12001	1	0001	02	0	123	01001		29.10.1945	CREA	Creatinine	99	99	umol/l	53.0 - 97.0	H		F
12001	1	0001	03	0	123	01001		29.10.1945	CREA	Creatinine	100	100	umol/l	53.0 -	H		F

How CDISC LAB & SDS/LB helped?...|



Phase III System (P3S)

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Menü / Logout

Mismatches

Einschränkungen

Studyno 12001 | Processno | Visit | Error Code | cleared status open

Einschränkungen aufheben | Download | Suchen

Anzahl der ausgewählten Probleme: 12

Filter by ???	Detected	Studyno	Processno	Visit	Error Code	Error Info	Clear Status Cleared MOD USR
Process Error	26.05.2005 10:14 Bearbeiten	12001	0002	02	507	Gender: F --> M	02.06.05 18:37 jwh
Process Error	26.05.2005 10:31 Bearbeiten	12001	0003	02	502	Screeningno: 01003 --> 01004	02.06.05 18:37 jwh Test PK
Process Error	26.05.2005 10:31 Bearbeiten	12001	0003	02	508	Birthday: 10.12.1969 --> 10.10.1969	02.06.05 18:37 jwh Test PK

A successful future for CDISC LAB...|

- CDISC LAB should consider the balance between biopharmaceutical Industry, CRO's & Laboratories
- Most databases work in relational or object models; this is in contradiction to CDISC LAB exchange format
- Eliminate redundant data in the current LAB structure
- Recommendation: split (Lab Data, Reference Ranges Data) and Methods Data consequently
- Many of unused variables in DB implementations
- Specific mandatory flags/descriptions: Selection of variables according to the needs of special users (sponsor, provider e.g.)
- This allows project specific views to the data.

CDISC brings the World together...|