

# Data Coding and Management

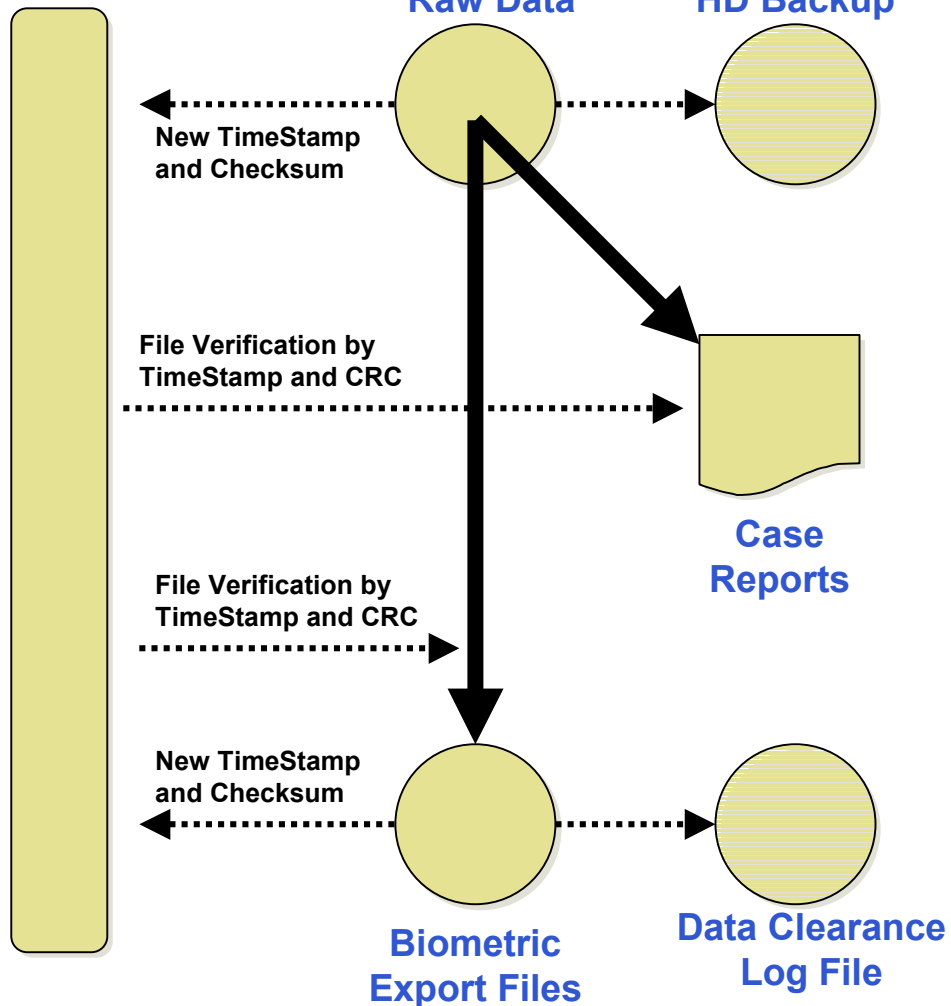
## **BeriSoft Cooperation**

Frankfurt, Germany

[www.erts.de](http://www.erts.de)

**5/4/2003**

## Audit Trail



## Audit Trail

- Independent binary file with time stamp and checksum of original file

## Raw Data

- ASCII result file created at end of test and stored on subject disk

## HD Backup

- Redundant copies on test station as data backup

## Case Report

- Printed summary report generated based on raw data

## Biometric Export Files

- Test-specific dependent variables calculated based on raw data that are verified against audit trail

## Data Clearance Log File

- Protocol of processed files

## Running Psychometric Test Battery based on ERTS

- Use validated software to collect performance data
- Print case reports on paper after each session
- Archive raw data and software

## Optional: BeriSoft Data Management

- Clear raw data and verify against audit trail
- Aggregate raw data into biometric export files
- Generate new audit trail entries for biometric export files

## Optional: Data Analysis and Reporting

- Load biometric export files as flat ascii files into SAS
- Verify imported files against audit trail
- Continue to work within SAS with audit trail

## What is CRC-32

- **CRC-32 is an acronym for the 32 bit Cyclical Redundancy Check algorithm. CRC-32 generally refers to a specific 32 bit CRC formula sanctioned by the CCITT, an international standards body primarily concerned with telecommunications. CRC-32 is used in communications protocols such as HDLC and ZMODEM to verify the integrity of blocks of data being transferred through various media.**

## Characteristics of CRC-32:

- **Every character in the file contributes to the CRC. Changing any character in the file should change the CRC.**
- **Relatively small changes in the file should always result in changes in the CRC.**
- **Probability of all 4,294,967,296 potential CRC values is about equal.**

## Our Solution

### Advantages of ASCII data files

- **All data files are readable and printable ASCII files open for human inspection**

### CRC-32 based audit trail

- **The CRC-32 algorithm is used to produce a "fingerprint" of each file.**
- **CRC values together with timestamps are stored in an independent binary audit file**

### Built-in file verification

- **Automatic generation of audit trail entries after each test session**
- **Comparison between actual CRC and logged CRC embedded in data clearing tool**
- **Automatic generation of additional audit trail entry for each biometric export file**

## At Lab

### System Access

- Access to PC or Laptop protected by BIOS password

### Audit Trail

- Independent binary encrypted audit trail that stores time stamp and CRC32 checksum of original raw data files

### User Identification

- None: Process does not require any modifications at CRO

### Data Protection

- Read-only flag for raw data files
- File versioning mechanism avoids overwriting

## At BeriSoft

### Transport Format

- WinZip protected by password

### Data Verification

- System embedded verification of file authenticity by comparing audit trail entries against actual checksum and timestamp

### Modifications / Aggregation

- Automatic transformations documented by meta data (ERTSCODE job files)
- Exceptions documented by Data Manager according to SOP
- Data Clearing Report lists all files being processed including verification status

## Electronic Data

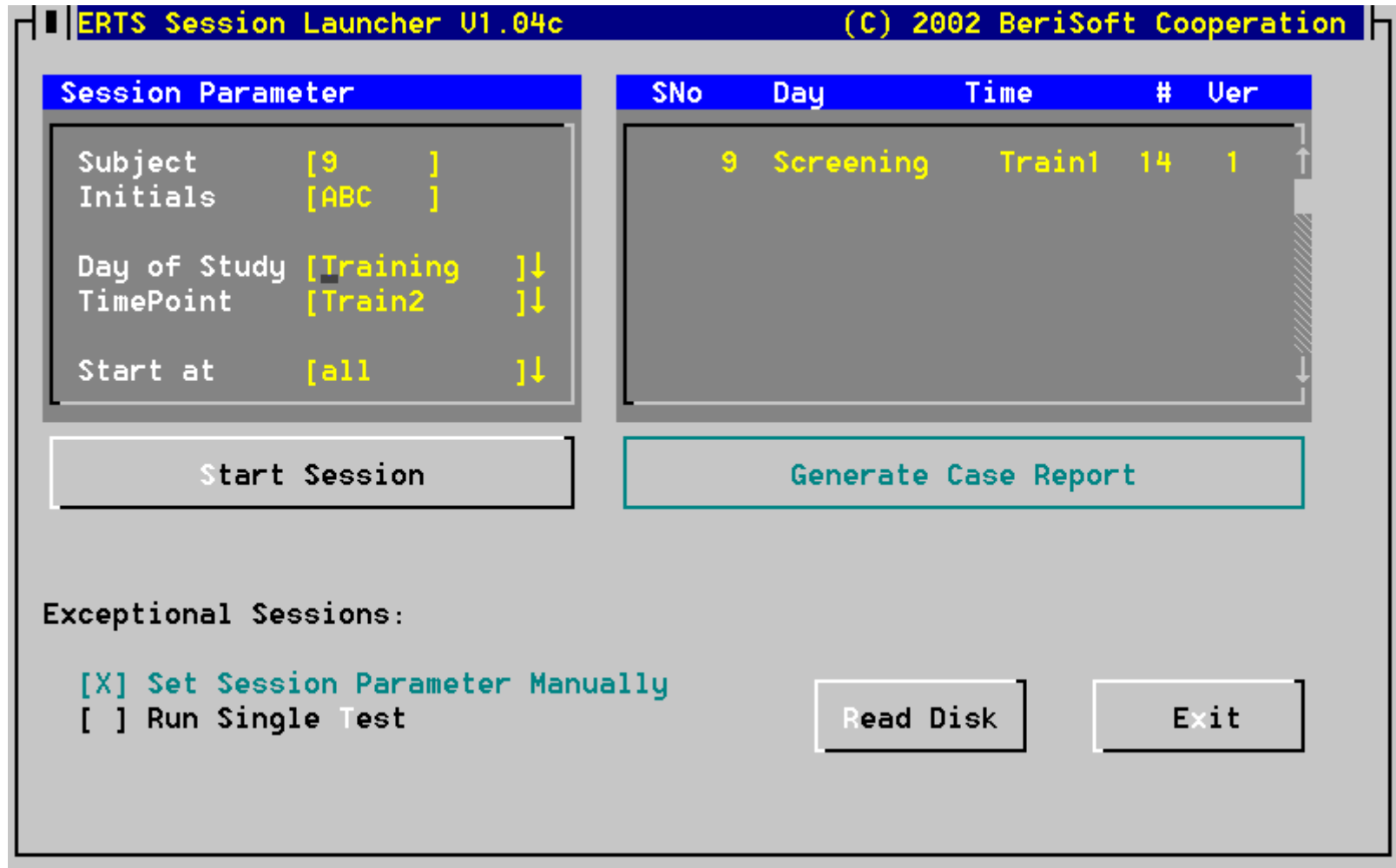
- Raw data generated in test session
- Biometric import files aggregated from raw data
- Audit trail log file

## Meta Data

- ERTS experiment control files to replicate psychometric test
- ERTSCODE job files to reconstruct data aggregation

## Software

- ERTS software to execute psychometric tests
- ERTSCODE software to process data
- VIEWAUDIT software tool to display audit trail



The session launcher provides a simple way of coding and starting sessions

## File Name

00007321.SRT

Subject

Test

Day of Study

Version

Time of Day

ERTS Session Launcher U1.04c

Session Parameter

Subject	[9 ]	
Initials	[ABC ]	
Day of Study	[Training ]	]↓
TimePoint	[Train2 ]	]↓
Start at	[all ]	]↓

Start Session

Exceptional Sessions:

- [X] Set Session Parameter Manu
- [ ] Run Single Test

## 99020411.SRT: External File Name and Time Stamp in Operating System

```

;   ERTS      : V3.34d =====
;   License   : CROs name
;   Session   : Simple Reaction to red square
;   Date      : Friday,  8. March 2002
;   Time      : 07:40:06
;   Call      : gc gk srt\sc srt\srt /EQ @9902 @4 @1 @RONWI @WR @all
;   Monitor   : VGA 640x480 (280x210 mm) with 59.7 Hz
;   -----

```

Log of how test was launched

SessCode	Blk	Spec	Trl	F1	Ans	R1	K1	Block	Trial
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	1	2	1	201.1	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	2	2	1	212.0	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	3	2	1	221.6	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	4	2	1	202.8	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	5	2	1	258.2	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	6	3	0	0	0	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	7	2	1	238.3	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	8	2	1	234.3	E3	SRT	SHOWLIG
#####_PLC2_99020411.SRT RONWI/ WR 08.03.02 07.40	1	1	9	2	1	230.2	E3	SRT	SHOWLIG

Study Code

FileName

Date/Time

PC#

Initials

Subject, Day, Time, Version, Test



## Data Management at BeriSoft Cooperation

### Transport

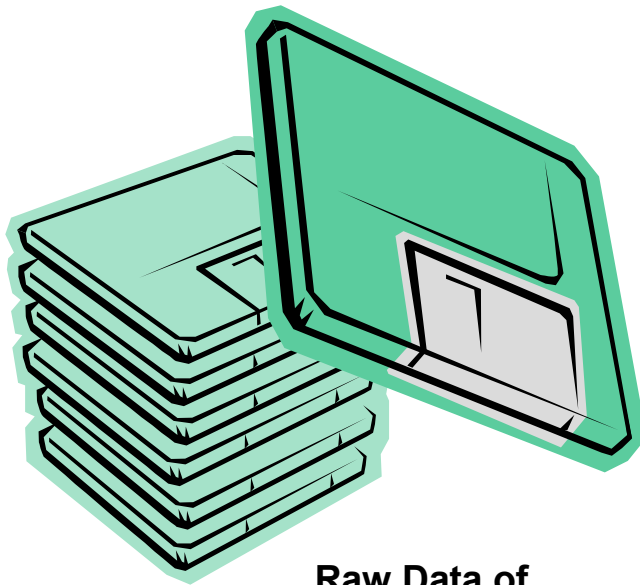
- Collecting raw data and audit trail across all subject disks (or test stations)
- Archiving in WinZip with password
- Sending by email attachment

### Clearing

- Checking for completeness and correspondence to study schedule
- Checking for corrupt files
- Checking for wrong coding
- Checking for correct performance

### Aggregation into biometric export file

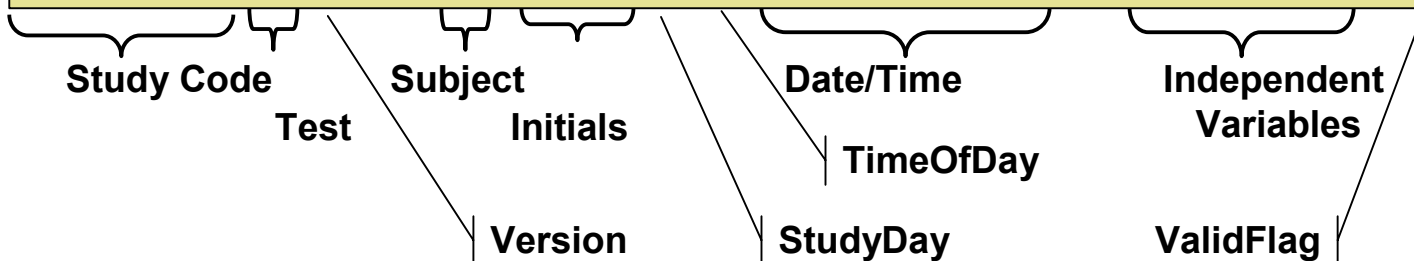
- File verification using audit trail
- Mapping of screening numbers to study code



Raw Data of  
all Sessions

Every data row represents one test session of one subject

STUDY	TEST	VER	GROUP	SUBJ	INISS	INI	SDAY	SHOUR	SESDATE	SESTIME	SRT_N	SRT_RT	SRT_NC	SRT_PE	SRT_VAL
#####	SRT	1	-1	225	SOUMA	MAS	1	1	18/10/02	14:07:15	40	273.9	39	2.5	1
#####	SRT	1	-1	225	SOUMA	MAS	2	1	06/11/02	10:17:37	40	234.8	40	0	1
#####	SRT	1	-1	225	SOUMA	MAS	3	1	07/11/02	07:35:54	40	271.9	38	5	1
#####	SRT	1	-1	225	SOUMA	MAS	4	1	09/11/02	07:56:13	40	262.3	40	0	1
#####	SRT	1	-1	225	SOUMA	MAS	4	2	09/11/02	11:44:59	40	319.3	39	2.5	1
#####	SRT	1	-1	225	SOUMA	MAS	4	3	09/11/02	19:57:23	40	305.6	40	0	1
#####	SRT	1	-1	225	SOUMA	MAS	5	1	13/11/02	08:02:37	40	317.5	39	2.5	1
#####	SRT	1	-1	225	SOUMA	MAS	5	2	13/11/02	12:07:47	40	341.5	39	2.5	1
#####	SRT	1	-1	225	SOUMA	MAS	5	3	13/11/02	20:52:41	40	437.8	37	7.5	1
#####	SRT	1	-1	225	SOUMA	MAS	6	1	17/11/02	07:56:29	40	316.4	40	0	1
#####	SRT	1	-1	225	SOUMA	MAS	6	2	17/11/02	11:53:55	40	290.4	39	2.5	1
#####	SRT	1	-1	225	SOUMA	MAS	6	3	17/11/02	20:05:52	40	308.1	39	2.5	1
#####	SRT	1	-1	225	SOUMA	MAS	7	1	20/11/02	07:24:28	40	270.9	40	0	1
#####	SRT	1	-1	226	BACEL	E-B	1	1	29/10/02	11:48:16	40	271.7	40	0	1
#####	SRT	1	-1	226	BACEL	E-B	2	1	06/11/02	10:23:57	40	272.6	40	0	1
#####	SRT	1	-1	226	BACEL	E-B	3	1	07/11/02	07:45:32	40	331.1	40	0	1
#####	SRT	1	-1	226	BACEL	E-B	4	1	09/11/02	08:10:18	40	296.6	38	5	1
#####	SRT	1	-1	226	BACEL	E-B	4	2	09/11/02	11:47:33	40	284	40	0	1



Every data row represents one processed file

FIX	STUDY	TEST	VER	GROUP	SUBJ	ORCID	INISS	INI	ODAY	OHOUR	SDAY	SHOUR	FILDATE	SESDATE	SESTIME
#####	SRT	1	1	225	33	SOUMA	MAS	1	1	1	1	1	18/10/02	18/10/02	14:07:15
#####	SRT	1	1	225	33	SOUMA	MAS	2	1	2	1	1	06/11/02	06/11/02	10:17:37
#####	SRT	1	1	225	33	SOUMA	MAS	3	1	3	1	1	07/11/02	07/11/02	07:35:54
#####	SRT	1	1	225	33	SOUMA	MAS	4	1	4	1	1	09/11/02	09/11/02	07:56:13
#####	SRT	1	1	225	33	SOUMA	MAS	4	2	4	2	2	09/11/02	09/11/02	11:44:59
#####	SRT	1	1	225	33	SOUMA	MAS	4	3	4	3	3	09/11/02	09/11/02	19:57:23
#####	SRT	1	1	225	225	SOUMA	MAS	5	1	5	1	1	13/11/02	13/11/02	08:02:37
#####	SRT	1	1	225	225	SOUMA	MAS	5	2	5	2	2	13/11/02	13/11/02	12:07:47
#####	SRT	1	1	225	225	SOUMA	MAS	5	3	5	3	3	13/11/02	13/11/02	20:52:41
#####	SRT	1	1	225	225	SOUMA	MAS	6	1	6	1	1	17/11/02	17/11/02	07:56:29
#####	SRT	1	1	225	225	SOUMA	MAS	6	2	6	2	2	17/11/02	17/11/02	11:53:55
#####	SRT	1	1	225	225	SOUMA	MAS	6	3	6	3	3	17/11/02	17/11/02	20:05:52
#####	SRT	1	1	225	225	SOUMA	MAS	7	1	7	1	1	20/11/02	20/11/02	07:24:28
#####	SRT	1	1	226	36	BACEL	E-B	1	1	1	1	1	29/10/02	29/10/02	11:48:16
#####	SRT	1	1	226	36	BACEL	E-B	2	1	2	1	1	06/11/02	06/11/02	10:23:57



Delta Flag **Comparison of file name/date, file content, and audit trail**

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