

Making Database QC easy, the PAREXEL way

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PAREXEL International Limited

What is it?

PAREXEL International

PAREXEL is one of the largest contract pharmaceutical outsourcing organisations in the world.

With a commitment to providing solutions that expedite time-to-market and peak market penetration, PAREXEL has developed significant expertise in clinical trials management, data management and biostatistical analysis amongst others

Headquartered near Boston, MA, PAREXEL operates in 53 locations throughout 33 countries around the world, and has approximately 4,600 employees

Clinical Trials Management

◆ Process

- Database Set Up (QC'd and Validated)
- Validation Programs Written and QC'd
- First CRF In house
- Data Entry
- Data Validated
- QC Data then Export back to Client

◆ Main Bottlenecks

- Validation Programs
- Final database QC

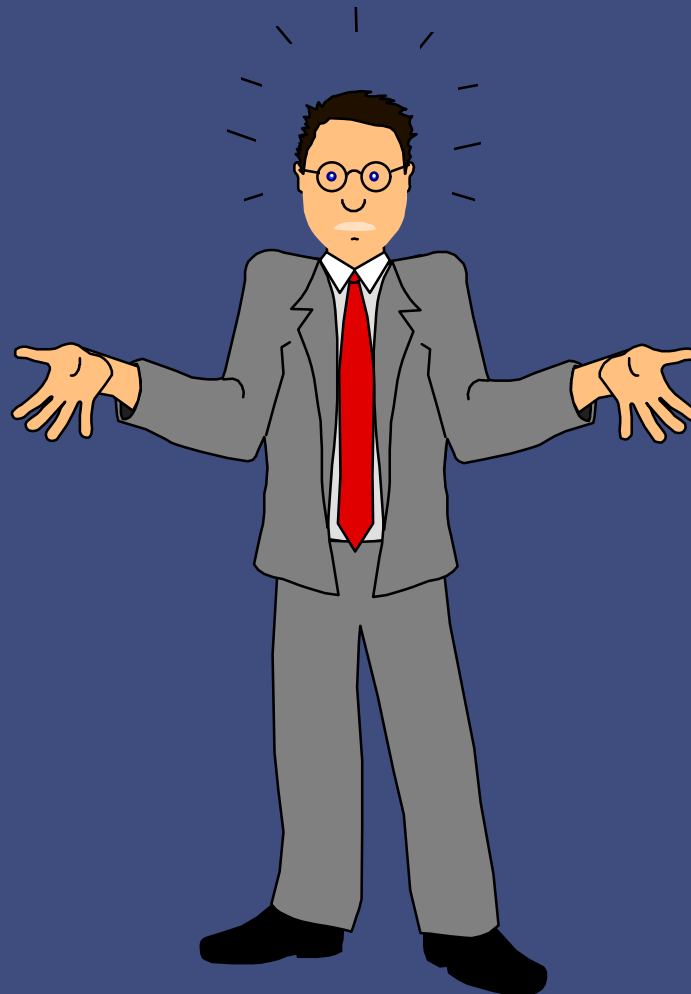
What do we need from database QC ?

- ◆ Ensure completeness and accuracy of the data in the database
- ◆ Rapid turn-around of processing at the final stage of data management
- ◆ Flag any problems / outstanding issues in the data prior to analysis

What difficulties may be encountered ?

- ◆ The time taken to generate the programs by skilled personnel can be great
- ◆ Possible changes to critical items late in the study
- ◆ Time taken to run the programs on a database can be very long and thus slow down turn-around times
- ◆ Huge bulk of work to be processed in a very short space of time means large amount of human resource needed

Problem



How PAREXEL overcame these problems

- ◆ **Make a simple to use interface that could be operated by data managers, thus removing the need for skilled SAS programmers**
- ◆ **Make amendments to the items required possible, whilst maintaining the original version for further use if needed**
- ◆ **Use SCL lists to store the item information**
- ◆ **Make the print process quicker as a result of the SAS procedures used**
- ◆ **Make it possible to do batches of output to spread the load more evenly**

QC Application

- ◆ The QC Application provides a simple data driven interface to allow **Data Managers** to produce listings for their studies.
- ◆ No specific SAS programming knowledge is required but the Data Manager is required to **understand data validation principles and their own database properties.**

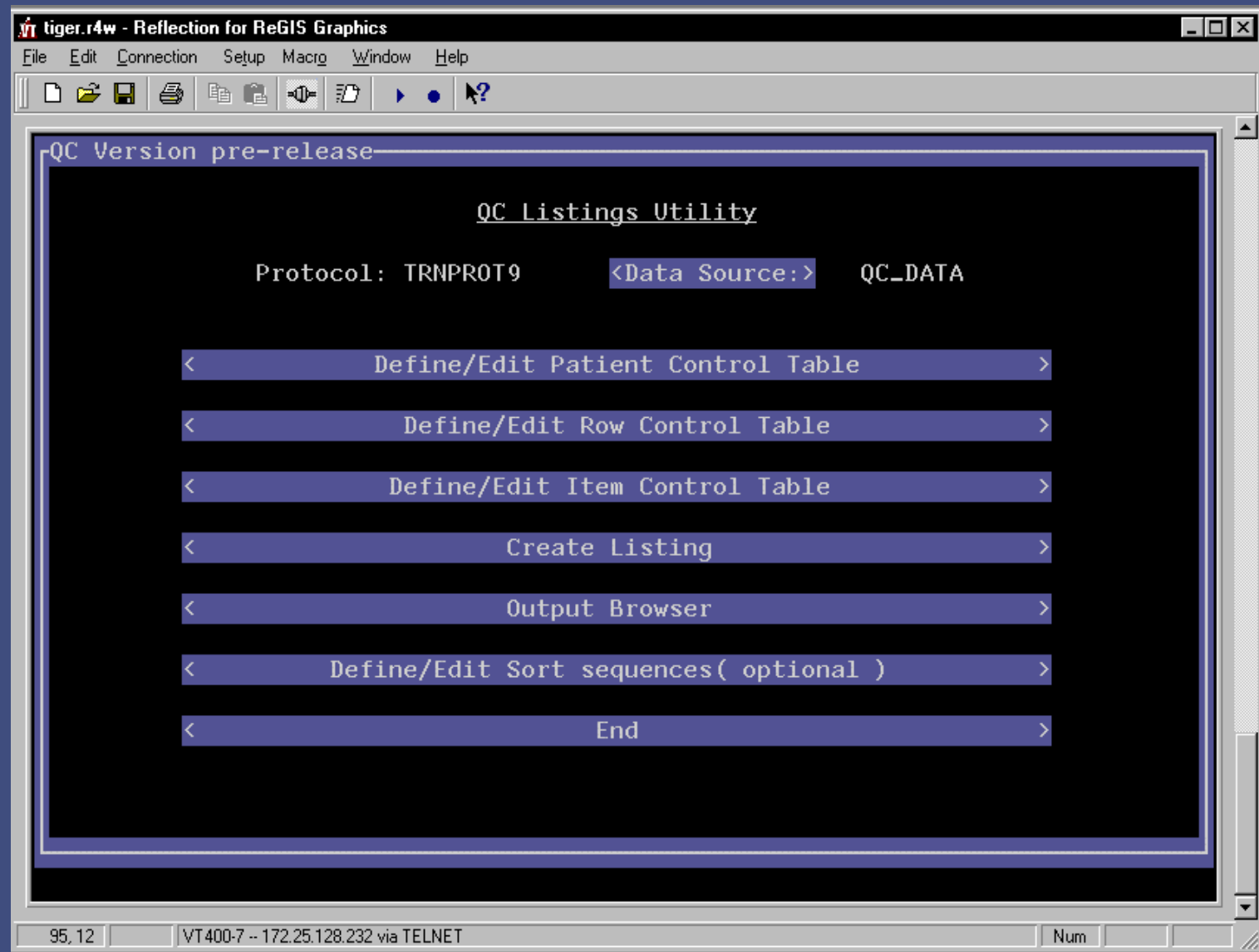
QC Application Overview

- ✓ The system uses 3 driving tables to produce the output
 - Patient control table
 - Row control table
 - Item control table
- ✓ The system is written using SAS/AF and runs on OpenVMS.
- ✓ The system allows re-running of old samples - the table may have been updated, but an old sample can still be referenced
- ✓ The system produces 4 output files
 - Listing
 - Messages
 - Item count
 - Population dataset

What to Know

- ◆ The Database
- ◆ Critical items
- ◆ or, which items are to be referenced and in what order

Let's have a look



Control tables

◆ Patient Control

- Uses a SAS dataset and an ID variable
- Can be subset
- Can be random or specific
- Can stratify
- Can specify size or percentage
- Labelled by user

◆ Row Control

- Uses SAS datasets or Clintrial database
- Can pick only certain visits / pages / forms
- Can reorder if required
- Labelled by user

Control tables

◆ Item Control

- Uses SAS datasets or Clintrial database
- Can restrict to certain items on a page / form
- Can reorder the items to reflect the CRF
- Labelled by user

Creating the listing

- ◆ The 3 tables can now be used to generate the listing
- ◆ Additional information can now be input to the system to refine the listing
 - Additional restriction across ALL datasets
 - Use batch (electronically) loaded data
 - Print out unscheduled data
 - Print out all form items
 - Use variable names or labels
 - Use codes or decodes

Creating the listing

tiger.r4w - Reflection for ReGIS Graphics

File Edit Connection Setup Macro Window Help

Generic QC list utility

Protocol = TRNPROT9

< Patient Control > -----

< Row Control > -----

< Item Control > -----

< Where Clause > None

Options:

- Exclude batch loaded data - Process unspecified rows

- List all referenced items

X Use Labels - Var. Names - use codes X use decodes

< Go > < Re-run >

624,9 VT400-7 -- 172.25.128.232 via TELNET Num

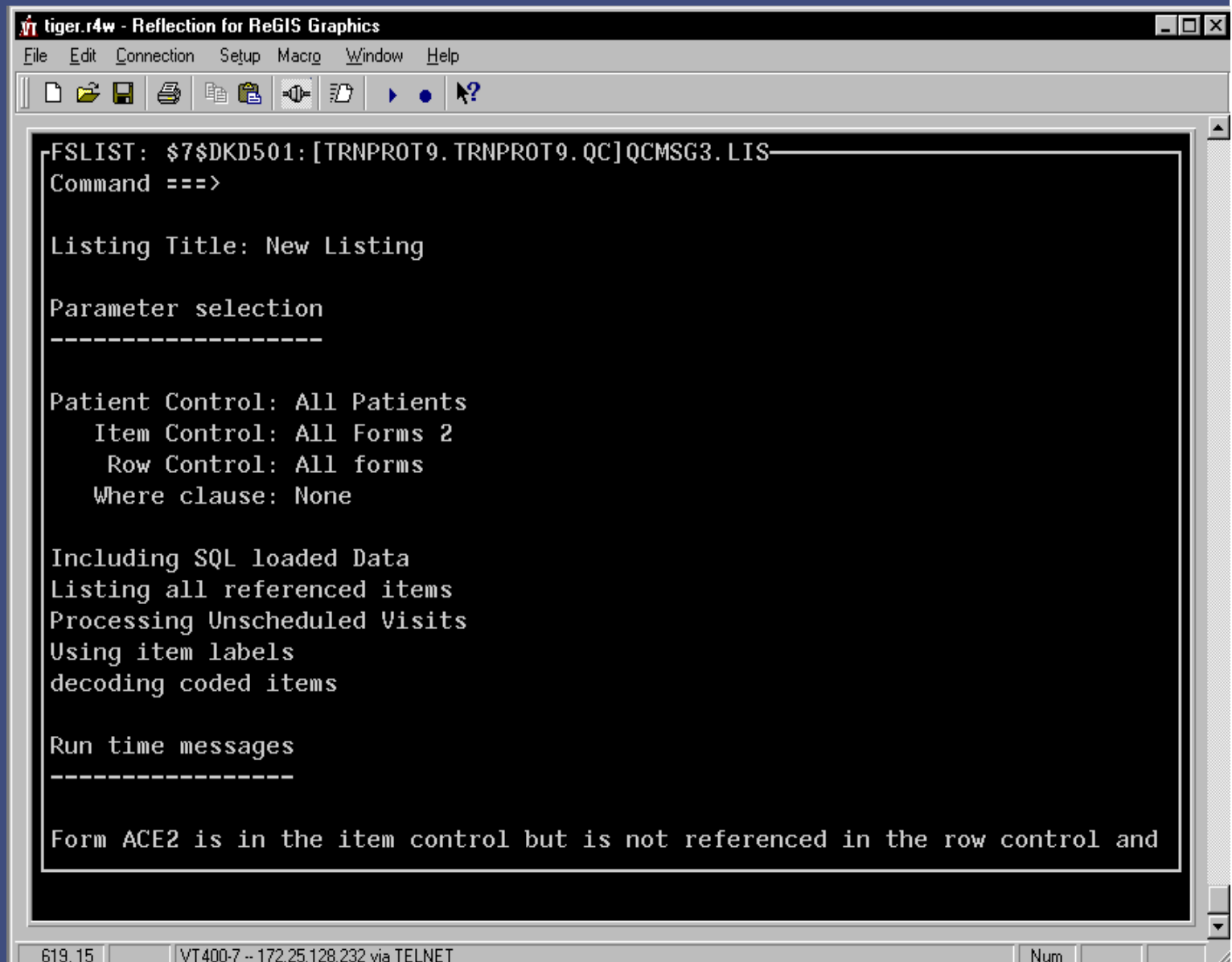
Output files

◆ Message file

- Contains information about the inputs and options selected
- Contains all run-time information - NOT information from the SAS log
- Contains information about the naming of the output files

Output files

◆ Message file



```
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File Edit Connection Setup Macro Window Help

FSLIST: $7$DKD501:[TRNPROT9.TRNPROT9.QC]QCMSG3.LIS
Command ==>

Listing Title: New Listing

Parameter selection
-----

Patient Control: All Patients
  Item Control: All Forms 2
  Row Control: All forms
  Where clause: None

Including SQL loaded Data
Listing all referenced items
Processing Unscheduled Visits
Using item labels
decoding coded items

Run time messages
-----

Form ACE2 is in the item control but is not referenced in the row control and
```

619, 15 | VT400-7 -- 172.25.128.232 via TELNET | Num

Output files

◆ Item count file

- Contains information about the items used and the number of times they were used
- Contains information about the naming of the output files

Output files

◆ Item count file

```
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File Edit Connection Setup Macro Window Help

FSLIST: $7$DKD501:[TRNPROT9.TRNPROT9.QC]QCCNT3.LIS
Command ==>
NOTE: At top.
QC Count information for TRNPROT9 run on 07AUG2001 at 14:20:38 by REESO

Listing Title: New Listing

Scheduled visit item counts
-----

Formname           Items Printed      Times used
VITALSA1           15                 582
VITALS3            15                  4
VITALS2A           15                 48
SPIN01             10                2890
SOECON06E          13                 24
SOECON06D          13                 24
SOECON06C          13                 24
SOECON06B          13                120
SOECON06A          13                 24
SDI01              12                 170
SCL9001            10                4860

619, 15 | VT400-7 -- 172.25.128.232 via TELNET | Num
```

Output files

- ◆ Listing file
 - Contains the selected items in the order that was specified

Output files

◆ Listing file

```
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File Edit Connection Setup Macro Window Help

FSLIST: $7$DKD501: [TRNPROT9. TRNPROT9. QC] QCLIST3. LIS
Command ==>

New Listing( PID1A="595.024.00261" ) Page 1

- OBS="0310.W1" and VISIT="VISIT3" and FORMNAME="CRF07B1" and FRMNAM1A="CRF07B
Identifier Visit Date of record Observation Code Form Name Clinic
00261 VISIT3 03JUL1998 0310.W1 CRF07B1 595
V etc. Start date Stop date Dose Level Number of units administered (ie 3
27JUN1998 03JUL1998 1 2.00
r 1/da Frequency Units (ie DAY for 1/day) Bottle Label
Day
-----
- OBS="0310.W1" and VISIT="VISIT3" and FORMNAME="COMPC04" and FRMNAM1A="COMPC
```

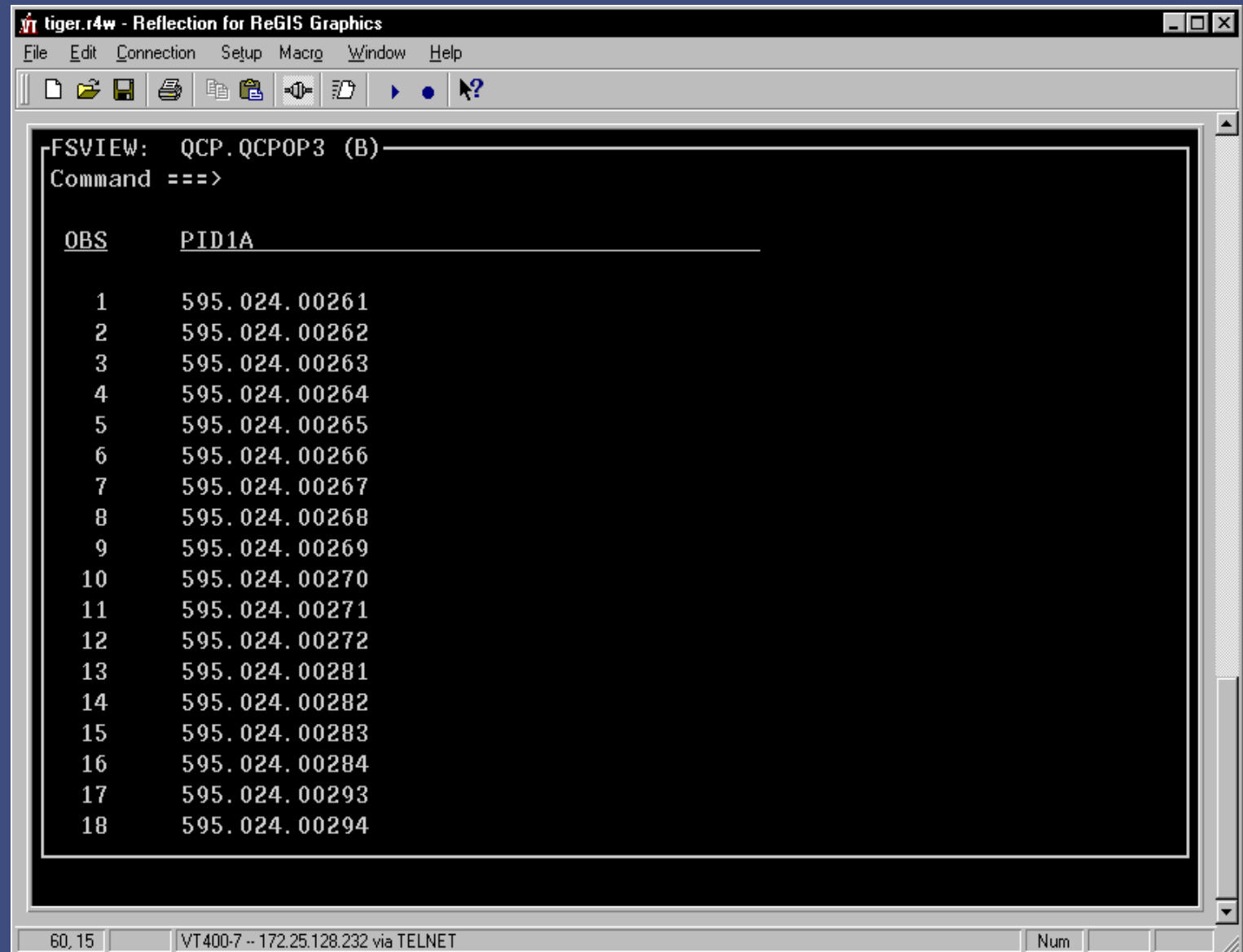
Output files

◆ Population dataset

- Contains the IDs (patients) that were actually used on the output
 - the patient control table may contain 10 entries, but only 4 of the patients may actually be found and subsequently produced - this dataset will contain only the 4, not the initial 10
- Allows the tracking of which IDs have had listings produced

Output files

◆ Population dataset



The screenshot shows a terminal window with a menu bar (File, Edit, Connection, Setup, Macro, Window, Help) and a toolbar. The main display area shows the following text:

```
FSVIEW: QCP.QCPOP3 (B)
Command ==>
```

OBS	PID1A
1	595.024.00261
2	595.024.00262
3	595.024.00263
4	595.024.00264
5	595.024.00265
6	595.024.00266
7	595.024.00267
8	595.024.00268
9	595.024.00269
10	595.024.00270
11	595.024.00271
12	595.024.00272
13	595.024.00281
14	595.024.00282
15	595.024.00283
16	595.024.00284
17	595.024.00293
18	595.024.00294

The status bar at the bottom displays '60, 15', 'VT400-7 -- 172.25.128.232 via TELNET', and a 'Num' button.

Overall

- ◆ The application is readily used in PAREXEL for producing high quality database listings for final QC
- ◆ Can also be used for standard listings for the day-to-day running of a study
- ◆ Much quicker to develop the suite of specifications for a study
- ◆ Much quicker to run than standard methods (datastep and proc print)
- ◆ Can re-run previous listings without needing to re-specify parameters (allows old control lists to be used)

QC Application Deployment

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Clinically thinking.™

Use of the QC Within PAREXEL



Questions?



Active Demonstrations

- ◆ Unfortunately not available here due to the operating system difficulties
- ◆ We are happy to arrange demonstrations in our offices
- ◆ Contacts
 - Sheffield - tel. 0114 225 1000
 - Oliver Rees
 - Sandy Meek
 - Uxbridge - tel. 01895 23 8000
 - Alistair Dootson
 - Siddick Mohamoodally
 - Nick Darwall-Smith