EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Clinical Trials Register: presentation of results information

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Compliance and Inspection Sector

Agenda

- Background
- Presentation of the results
- Usability testing

EU Clinical Trials Register

Clinicaltrialsregister.eu

Search for Clinical Trials

Search Reset Advanced Search

Examples: Cancer AND Drug Name. Pneumonia AND Sponsor Name.
Click here for more information

Search Tips: Under advanced search you can use filters for Country, Age Group, Gender, Trial Phase, Trial Status, Date Range, Rare Diseases and Orphan Designation. For these items you should use the filters and not add them to your search terms in the text field.

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Summary

EudraCT Number:	2004-000139-27
Sponsor's Protocol Code Number:	A509 1018
National Competent Authority:	Sweden - MPA
Clinical Trial Type:	EEA CTA
Trial Status:	Completed
Date on which this record was first entered in the EudraCT database:	2004-07-23

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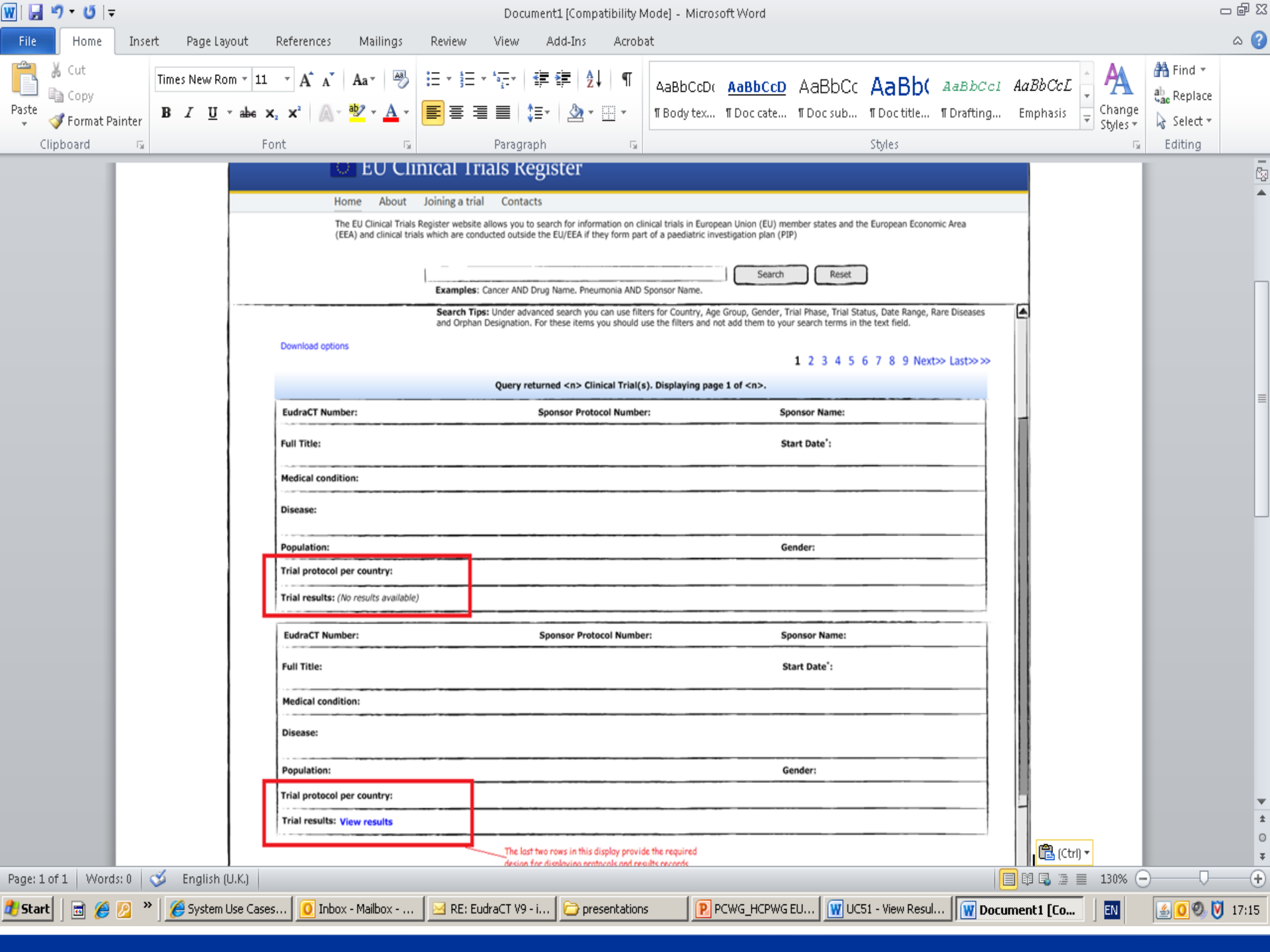
A. PROTOCOL INFORMATION
B. SPONSOR INFORMATION
C. APPLICANT IDENTIFICATION
D. IMP IDENTIFICATION
D.8 INFORMATION ON PLACEBO
E. GENERAL INFORMATION ON THE TRIAL

Background: EU Clinical Trials Register and Results

Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006

http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf

The EudraCT database will be updated and sponsors will be able to enter and publish the results of trials they conducted.



EU Clinical Trials Register

Home About Joining a trial Contacts

The EU Clinical Trials Register website allows you to search for information on clinical trials in European Union (EU) member states and the European Economic Area (EEA) and clinical trials which are conducted outside the EU/EEA if they form part of a paediatric investigation plan (PIP)

Search Reset

Examples: Cancer AND Drug Name. Pneumonia AND Sponsor Name.

Search Tips: Under advanced search you can use filters for Country, Age Group, Gender, Trial Phase, Trial Status, Date Range, Rare Diseases and Orphan Designation. For these items you should use the filters and not add them to your search terms in the text field.

Download options

1 2 3 4 5 6 7 8 9 Next>> Last>>>

Query returned <n> Clinical Trial(s). Displaying page 1 of <n>.

EudraCT Number: **Sponsor Protocol Number:** **Sponsor Name:**

Full Title: **Start Date*:**

Medical condition:

Disease:

Population: **Gender:**

Trial protocol per country:

Trial results: *(No results available)*

EudraCT Number: **Sponsor Protocol Number:** **Sponsor Name:**

Full Title: **Start Date*:**

Medical condition:

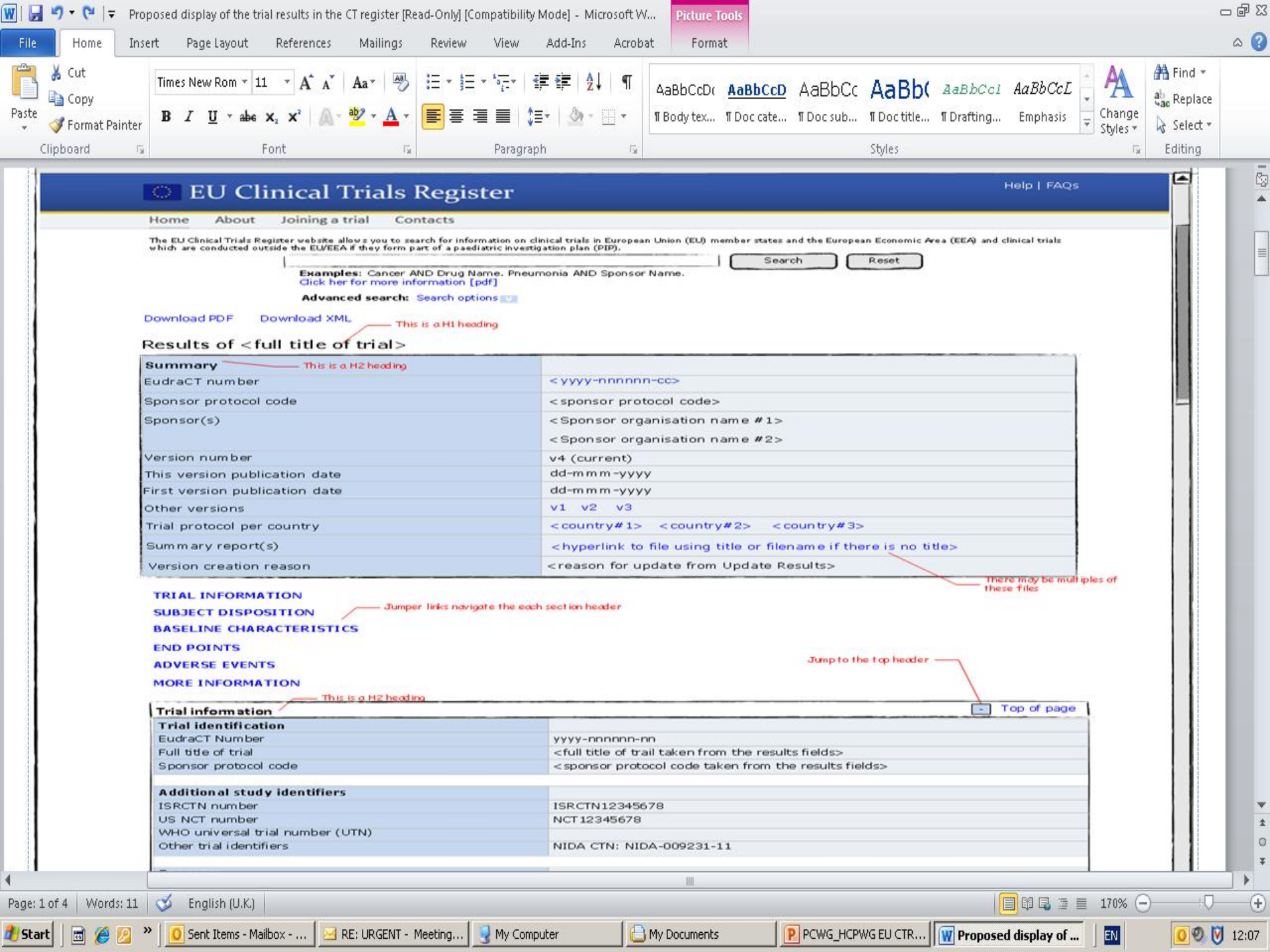
Disease:

Population: **Gender:**

Trial protocol per country:

Trial results: View results

The last two rows in this display provide the required design for displaying protocols and results records


Proposed display of the trial results in the CT register [Read-Only] [Compatibility Mode] - Microsoft W...
Picture Tools
File
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The EU Clinical Trials Register website allows you to search for information on clinical trials in European Union (EU) member states and the European Economic Area (EEA) and clinical trials which are conducted outside the EU/EEA if they form part of a paediatric investigation plan (PIP).
Search
Reset
Examples: Cancer AND Drug Name. Pneumonia AND Sponsor Name.
Click her for more information [pdf]
Advanced search: Search options
Download PDF
Download XML
This is a H1 heading
Results of <full title of trial>
Summary
This is a H2 heading
EudraCT number
<yyyy-nnnnnn-cc>
Sponsor protocol code
<sponsor protocol code>
Sponsor(s)
<Sponsor organisation name #1>
<Sponsor organisation name #2>
Version number
v4 (current)
This version publication date
dd-mmm-yyyy
First version publication date
dd-mmm-yyyy
Other versions
v1 v2 v3
Trial protocol per country
<country#1> <country#2> <country#3>
Summary report(s)
<hyperlink to file using title or filename if there is no title>
Version creation reason
<reason for update from Update Results>
There may be multiples of these files
TRIAL INFORMATION
SUBJECT DISPOSITION
BASELINE CHARACTERISTICS
END POINTS
ADVERSE EVENTS
MORE INFORMATION
Jumper links navigate the each section header
Jump to the top header
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Trial information
Top of page
Trial identification
EudraCT Number
yyyy-nnnnnn-nn
Full title of trial
<full title of trail taken from the results fields>
Sponsor protocol code
<sponsor protocol code taken from the results fields>
Additional study identifiers
ISRCTN number
ISRCTN12345678
US NCT number
NCT12345678
WHO universal trial number (UTN)
Other trial identifiers
NIDA CTN: NIDA-009231-11
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Start
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My Documents
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Proposed display of ...
EN
12:07

	scientific contact email address>
Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	<Yes/No>
EMA paediatric investigation plan number(s)	EMEA-nnnnnn-PIPnn-nn, EMEA-nnnnnn-PIPnn-nn
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Results analysis stage	
Analysis stage	Final
Date of interim/final analysis	dd-mmm-yyyy
Is this the analysis of the primary completion data?	Yes
Primary completion date	dd-mmm-yyyy
Global end of trial reached?	<Yes/No>
Global end of trial date	dd-mmm-yyyy
General information about the trial	
Main objective of the trial	<objective>
Actual start date of recruitment	dd-mmm-yyyy
Long term follow-up planned	Yes
Long term follow-up rationale	<rationale #1>, <rationale #2>
Long term follow-up duration	<n> <duration units>
Independent data monitoring committee (IDMC) involvement?	<Yes/No>
Protection of trial subjects	<details>
Background therapy	<details>
Evidence for comparator	<details>
Population of trial subjects	
Number of subjects enrolled per country	
Country: Number of subjects enrolled	<country #1>: <number of subjects enrolled>
Country: Number of subjects enrolled	<country #2>: <number of subjects enrolled>
Worldwide total number of subjects	<worldwide number of subjects>
EEA total number of subjects	<EEA number of subjects>
Number of subjects enrolled per age group	
In utero	<number of subjects for category #1>
Preterm newborn - gestational age < 37 wk	<number of subjects for category #2>
Newborns (0-27 days)	<number of subjects for category #3>
Infants and toddlers (28 days-23 months)	<number of subjects for category #4>
Children (2-11years)	<number of subjects for category #5>
Adolescents (12-17 years)	<number of subjects for category #6>
Adults (18-64 years)	<number of subjects for category #7>
From 65 to 84 years	<number of subjects for category #8>
85 years and over	<number of subjects for category #9>

This is a H2 heading

Usability testing

A small group including Patient Organisations and Sponsors will be asked to review the proposed display of the results to assess its usability. Further testing will be done once the system has been launched and that real data are available.