PDS290 Focused Usability Test of colour-blind individuals' ability to differentiate between Tresiba® 100 units/mL FlexTouch®, Tresiba® 200 units/mL FlexTouch®, and NovoRapid® FlexPen® pen-injectors and cartons

First published: 28/04/2014

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4122

Study ID

15966

DARWIN EU® study

No

Study countries

Denmark

Germany

United Kingdom

Study description

The test objective is to investigate whether people suffering from red-green colour-blindness can differentiate between different pen-injectors and their respective packages (i.e., cartons).

Study status

Finalised

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Multiple centres: 10 centres are involved in the study

Contact details

Study institution contact

Global Clinical Registry (GCR) Novo Nordisk

clinicaltrials@novonordisk.com

Study contact

clinicaltrials@novonordisk.com

Primary lead investigator

Global Clinical Registry (GCR, 1452) Novo Nordisk

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/07/2013

Study start date

Actual: 02/05/2014

Data analysis start date

Actual: 22/05/2014

Date of final study report

Actual: 18/08/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

UT117-test-protocol-final-version-2-12-dec-2013-Redacted.pdf (2.66 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Medical device

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Device usability study

Data collection methods:

Primary data collection

Main study objective:

The test objective is to investigate whether people suffering from red-green colour-blindness can differentiate between different pen-injectors and their respective packages (i.e. cartons).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Device usability study

Population studied

Short description of the study population

People with diabetes who were red-green colour blind.
Individuals with Type 1 or Type 2 diabetes who currently self-administer insulin daily using a prefilled pen-injector, vial and syringe, or insulin pump, or who have self-administered insulin in the past were included. Participants with other

mild and moderate visual impairments (e.g., near-sightedness, glaucoma) were included to the extent that they were identified during participant recruitment. All participants who were able to read the numerals displayed in the prefilled pen-injector’s dose window (e.g., 16). Participants with various levels of education were included.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

15

Study design details

Data analysis plan

After completing the test, test data will be analysed and consolidated as follows:- Review test data and apply professional judgment to describe and determine the root cause(s) for use errors, close calls, and operational difficulties- Count the total number of each type of use error, close call, and operational difficulty- Calculate the means and ranges of the ratings and visualize the data as a bar graph- Summarize participant demographic / background information

Documents

Study results

ut117-focused-usability-test-report-redacted.pdf (820.08 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Test consists of a hands-on session and a post-test interview. The hands-on portion of the test will require all participants to perform a total of 3 carton differentiation tasks and 3 pen-injector differentiation tasks. After the participant performs all tasks and other aforementioned activities, a post-test (i.e. exit) interview will be conducted.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown