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

PURI

https://redirect.ema.europa.eu/resource/15966

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

First published: 01/02/2024

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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

Study contact

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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

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