Trial Description

Title

Clinical study of the MosaiQ™ Platform, comprised of a fully automated instrument and MosaiQ™ Microarray IH (Immunohaematology), (EU: MACH 1 Study)

Trial Acronym

MosaiQ

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

**This study is a
Clinical Performance Evaluation Study with the MosaiQ™ Platform.
The MosaiQ™ Platform is an investigational IV device comprising an instrument for testing blood grouping (detection of the presence or absence of targeted antigen/ antibody specificities printed on a disposable single use microarray).**

**The instrument is intended to test an extensive range of antigens and antibodies on blood samples from individuals for routine testing during blood donation and or routine pre- transfusion testing.
• Comparison of test results between the IVD Investigational MosaiQ™ Platform and the approved on site IVD instruments, reagents, assays, and/ or manual testing, as required.**

The instrument performs as expected when used in accordance with its Instructions For Use (IFU).

Performance evaluation will be conducted at both internal (Sponsor) and external (Donor/Patients) test sites and is designed, where applicable, to demonstrate:

o Comparability of performance between the MosaiQ™ Instrument(s) and existing licensed instruments/reagent(s) marketed for the same intended use (comparator instruments/reagent(s))

**o Testing will also reflect the following variations:
- Lot to Lot.
- Occasion to Occasion.
- Operator to Operator.
- Potential interference effects arising from laboratory tube storage conditions/ anticoagulants.**

IH Study minimum total samples: ABO: 3000 / Cc Ee K: 1000 / DAT: 1000 / Cw k Fya Fyb Jka Jkb M N S s P1 Lea Leb: 600 / Lub Dia Kpa Jsa: 100 (see 8.3.Testing).

Samples from donors (donor sites) who have made a blood donation to transfusion services and whose redundant, anonymous blood samples can be used for research purposes.

Organizational Data

- DRKS-ID: **DRKS00014656**
- Date of Registration in DRKS: **2018/04/24**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **Bo/15/2017 , Ethikkommission bei der Ärztekammer Niedersachsen**

Secondary IDs

Health condition or Problem studied

- Free text: **Blood Group serology**

Interventions/Observational Groups

- Arm 1: **Samples from donors (donor sites) who have made a blood donation to transfusion services and whose redundant, anonymous blood samples will be tested for Research purposes. Test Parameters are infectious parameters as already tested with a comparator device, i.e. devices currently approved on market, instruments, reagents, assays in use at site. The results will be compared.**
  Only Anonymised (De-Identified) samples are used in the study.
  MosaiQ™ System is intended for use as an automated method for immunohematology testing and or infectious disease screening of red blood cells and/ or plasma, in the blood center setting. Samples are collected during routine phlebotomy of a donor during blood collection at the blood Center.
  The following blood Group Antigens are measured in the study time:
  ABO
  Cc Ee K
  DAT
  Cw k Fya Fyb Jka Jkb M N S s P1 Lea Leb
  Lub Dia Kpa Jsa

Characteristics

-

Study Type: **Non-interventional**

- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Immunohaematology (IH):
To compare the MosaiQ™ Platform to CE marked instruments/assays currently on the market.

Instrument Data will be entered into a central database using a printed copy of the instrument results- this will be the source document. Comparator Data will be entered on an excel spreadsheet – this will be the source document and subsequently entered into a central database. Sites will be provided independent laptops for data entry, and a USB sticks to remove data from the site and upload to the EDC system.

The test results will be evaluated after finishing the tests.

Secondary Outcome

To evaluate the user performance of the microarray for each tested category, on the MosaiQ™ Platform.

Countries of recruitment

- UK **United Kingdom**
- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- other • **NHS Blood and Transplant; 500 North Bristol Park; Bristol BS34 7QH; UK, Bristol BS34 7QH; UK**
- other • **Interregionale Blutspende SRK AG; Murtenstrasse 133; 3008 Bern; Switzerland, 3008 Bern; Switzerland**

- other • **Blutspendedienst der Landesverbände des DRK Niedersachsen, Sachsen-Anhalt, Thüringen, Oldenburg und Bremen gGmbH; 31830 Springe; Germany, 31832 Springe, Germany**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/05/24**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **72 Years**

Additional Inclusion Criteria

Not applicable. This is a Performance Evaluation of an in-vitro diagnostic. Samples from donors (donor sites) who have made a blood donation to transfusion services and whose redundant, anonymous blood samples can be used for research purposes will be tested. Only samples from healthy donors who fulfill the donation criteria of DRK-Blutspendedienst NSTOB will be accepted (see also Guidelines Hemotherapy)

Exclusion criteria

Not applicable. This is a Performance Evaluation of an in-vitro diagnostic. Samples from donors (donor sites) who have made a blood donation to transfusion services and whose redundant, anonymous blood samples can be used for research purposes will be tested. Samples from donors who do not fulfill the donation criteria of DRK-Blutspendedienst NSTOB will not be accepted (see also Guidelines Hemotherapy)

Addresses

- **Primary Sponsor**

  Quotient Business Park Terre Bonne
  Mr. Jim Donelly
  Route de Crassier 13
  1262 Eysins
  Switzerland

  Telephone: **[---]***

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■ **Contact for Scientific Queries**

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URL: **www.blutspende-nstob.de**

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URL: **www.blutspende-nstob.de**

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Quotient Business Park Terre Bonne
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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **2018/06/18**

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum MosaiQ 27.04.2017**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*