Wrightington, Wigan and Leigh NHS Foundation Trust

Research and Clinical Trials

Welcome to the Clinical Trials Unit

The Clinical Trials Department is based at Wrightington Hospital and supports the Research and Development strategy of Wrightington, Wigan and Leigh NHS Foundation Trust.

Research is a core activity of the Trust and is central to the promotion, provision, and continuous improvement in the quality and safety of all aspects of the services we offer.

Over the years, the Clinical Trials Unit has built up a service which is now attracting international repute for its capability in conducting high quality, ethical and clinically relevant research within our community.

All research trials conducted at Wrightington, Wigan and Leigh NHS Trust are done so to international standards by experienced and qualified staff who are also familiar with robust record information systems.

There are many ways to get involved with research

Participation in research puts patients and the healthcare team at the forefront of evolving new treatments.

You could join a Patient and Public Involvement group. This is led by Doctor Jane Martindale at Wrightington Hospital and you can contact her via researchadmin@wwl.nhs.uk

You may wish to take part in a research trial for a specific treatment. You are welcome to contact researchadmin@wwl.nhs.uk to discuss this. Alternatively you may complete a contact form asking for a member of the team to contact you and discuss your needs.

What are Clinical Trials?

Clinical trials often involve patients with specific health conditions who can potentially benefit from receiving otherwise unavailable treatments.

During the clinical trial, the investigators:

- recruit patients with the predetermined characteristics,
- administer the treatment(s), and
- collect data on the patients' health for a defined time period.

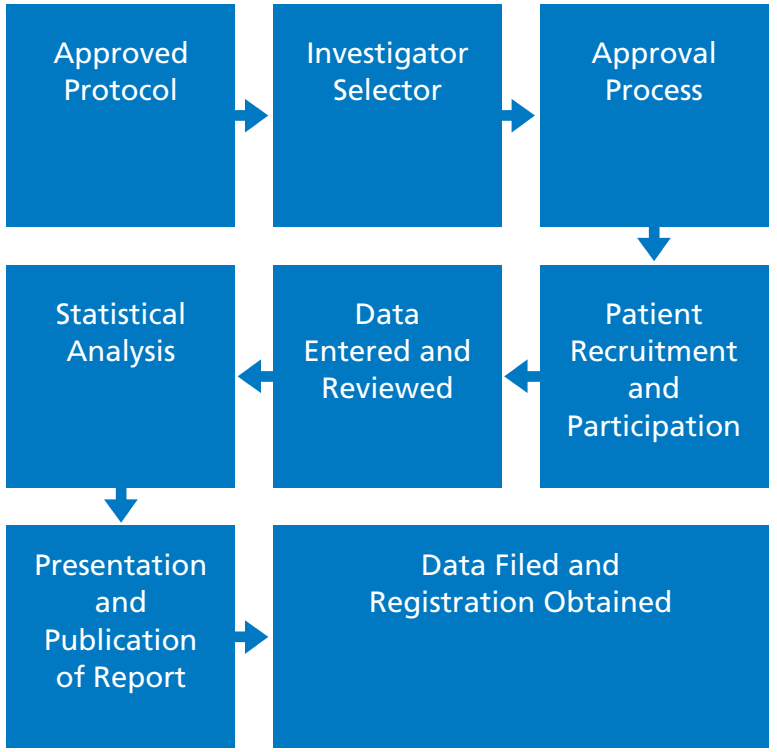
These patients are voluntary and they are not paid for participating in clinical trials.

The data includes measurements like:

- Blood Pressure,
- ECG,
- Heart Rate
- concentration of the study drug in the blood, and
- whether the patient's health improves or not.

The researchers send the data to the trial sponsor who then analyses the pooled data.

The table below shows the clinical trials process.



Examples

Below are some examples of what a clinical trial may be designed to do.

- Assess the safety and effectiveness of a different dose of a medication than is commonly used (e.g., 10 mg dose instead of 5 mg dose)
- Assess the safety and effectiveness of a new medication or device on a patient with a specific illness (e.g. patients who have been diagnosed with Rheumatoid Arthritis
- Assess whether the new medication or device is more effective for the patient's condition than the standard therapy
- Assess the safety and effectiveness of a medication or device which is already on the market for a new indication, (i.e. a disease for which the drug is not specifically approved)
- Observational study collects anonymised information about a disease and its impact on your life. This information will lead the research community to develop treatments and management systems in controlling and potentially eradicating the disease in the future.

Benefits of our Clinical Trials Department

The Clinical Trial Unit provides a trial management service which includes the provision of support to both patients and doctors in carrying out high quality, ethical and clinically relevant research in our local community.

Staff within the department have a strong knowledge base of research methodology and Trust procedures. They have an understanding of the needs of the Sponsor, Investigator and the Participants.

This provides for the following:

- Ensures respect for the dignity, rights, safety and wellbeing of study participants
- Facilitating patient liaison and recruitment
- Employs dedicated , experienced and qualified research nurses
- Maintains and monitors quality control by adhering to Standard Operating Procedures (SOP's)
- Ensures that governance issues are appropriately managed
- Ensures that study documentation is correctly managed during a trial and appropriately archived following a trial.
- Provides the necessary assurance that all clinical trials are carried out in a safe and ethical way
- Provides transparency to all concerned parties
- Promotes and establishes ICH GCP compliance in accordance with the requirements of research governance.

ICH GCP is a European standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected.

- Ensures that support services such as Radiology, Pharmacy and the Laboratory are consulted appropriately during the planning of the Clinical Trial
- Provides a single accessible point of contact
- A definitive point of contact for all issues pertaining to Clinical Trials
- Access to a large range of trials which covers a comprehensive range of hospital specialities

Our award winning Clinical Trials team

Current Trial Activity

Rheumatoid conditions such as:

- Rheumatoid Arthritis
- Lupus
- Ankylosing Spondylitis
- Psoriatic Arthritis
- Digital Ulceration
- Observational studies

Orthopaedics

- Hip Replacement
- Revision surgery
- Knee Replacement
- Observational studies
- Ankle Replacement versus Fusion treatment
- DuPuytrens

Cardiac
Diabetes
ENT
Gastroenterology
Opthalmology
Dental
Respiratory
Infection
Dermatology
Paediatric
Fertility treatment
Cancer

If you have a disease area which is not mentioned but would like to find out more please contact researchadmin@wwl.nhs and a member of the team will contact you for a confidential discussion.

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your hospitals, your health, our priority