PiCC United

Our simple guide to Clinical Trials

Clinical trials are vital research studies that help develop new treatments and improve healthcare. This guide explains the process in simple terms for patients and the public.

What are Clinical Trials?

Research Studies

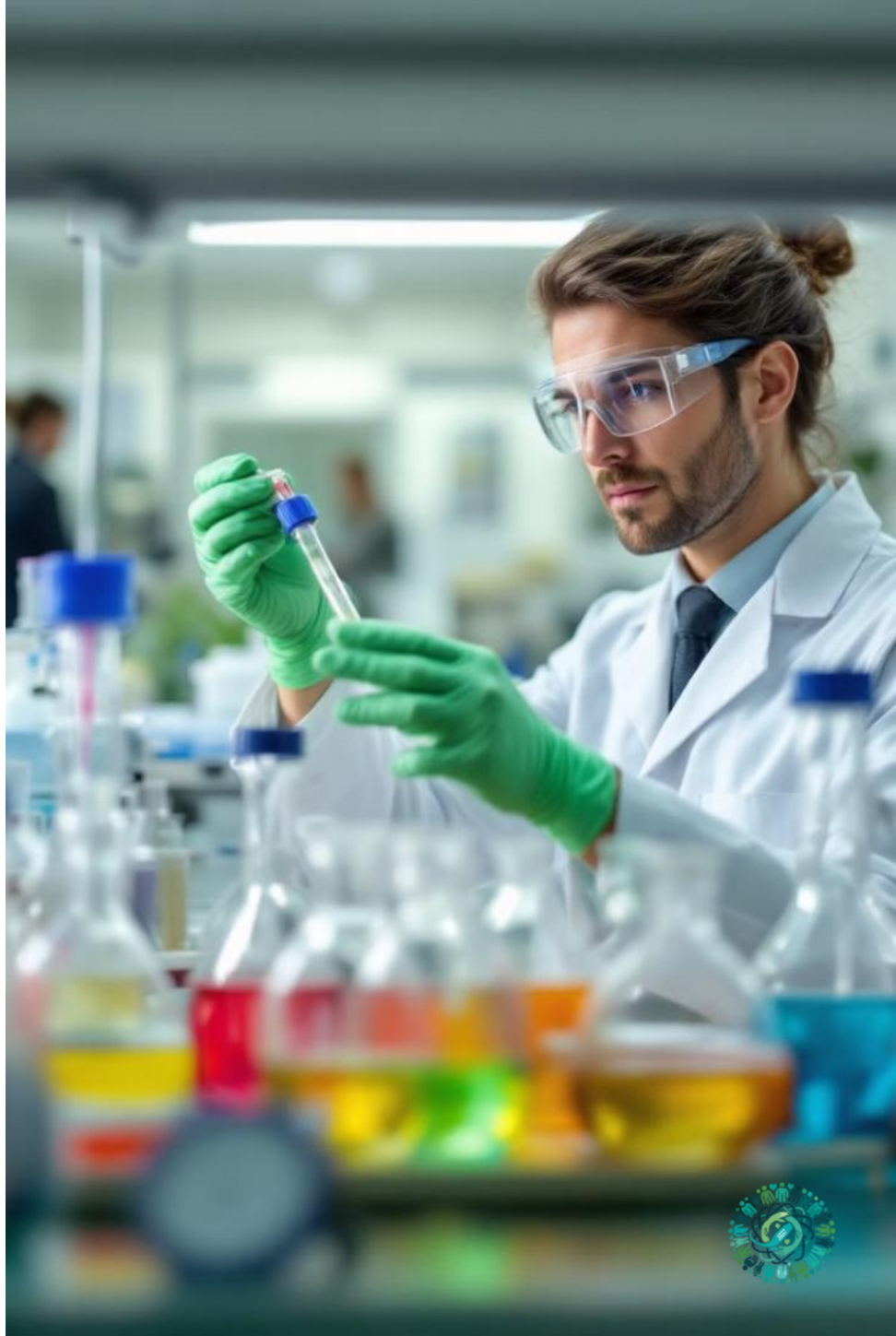
Tests of new medical treatments, drugs, or devices conducted by researchers and doctors.

Improving Healthcare

Finding better ways to prevent, diagnose, or treat diseases through careful testing.

Real Examples

Testing a new diabetes medication or a device that detects cancer earlier than current methods.



Phases of a Clinical Trial

Phase 1: Safety Testing

A small group of volunteers, 20 - 80 participants, are involved to test for side effects. The focus is on safety.

Phase 2: Effectiveness

100-300 patients test if the treatment works for their condition and learn more about side effects.

Phase 3: Comparison

1000+ patients compare the new treatment to existing options. This confirms how well the treatment works and checks for any rare side effects.

Phase 4: Long-term Monitoring

After approval, researchers track long-term effects in real-world use.

Who Can Participate?

Inclusion Criteria

Participants in a study must have certain characteristics or factors to be able to take part, these can include:

- Presence of particular disease or condition or severity type.
- Demographic characteristics, e.g., age.
- Medical history and/or previous treatments.

These ensure the the study focuses on the right population to assess the safety and effectiveness of a new treatment.

Exclusion Criteria

Factors that sometimes prevent participation:

- Certain medications.
- Other health conditions.
- Pregnancy or breastfeeding.
- Substance abuse (alcohol or drugs).

These protect participant safety and ensure accurate results.

What to Expect as a Participant

Information Session

You'll learn about the trial's purpose, procedures, risks, and benefits.

Informed Consent

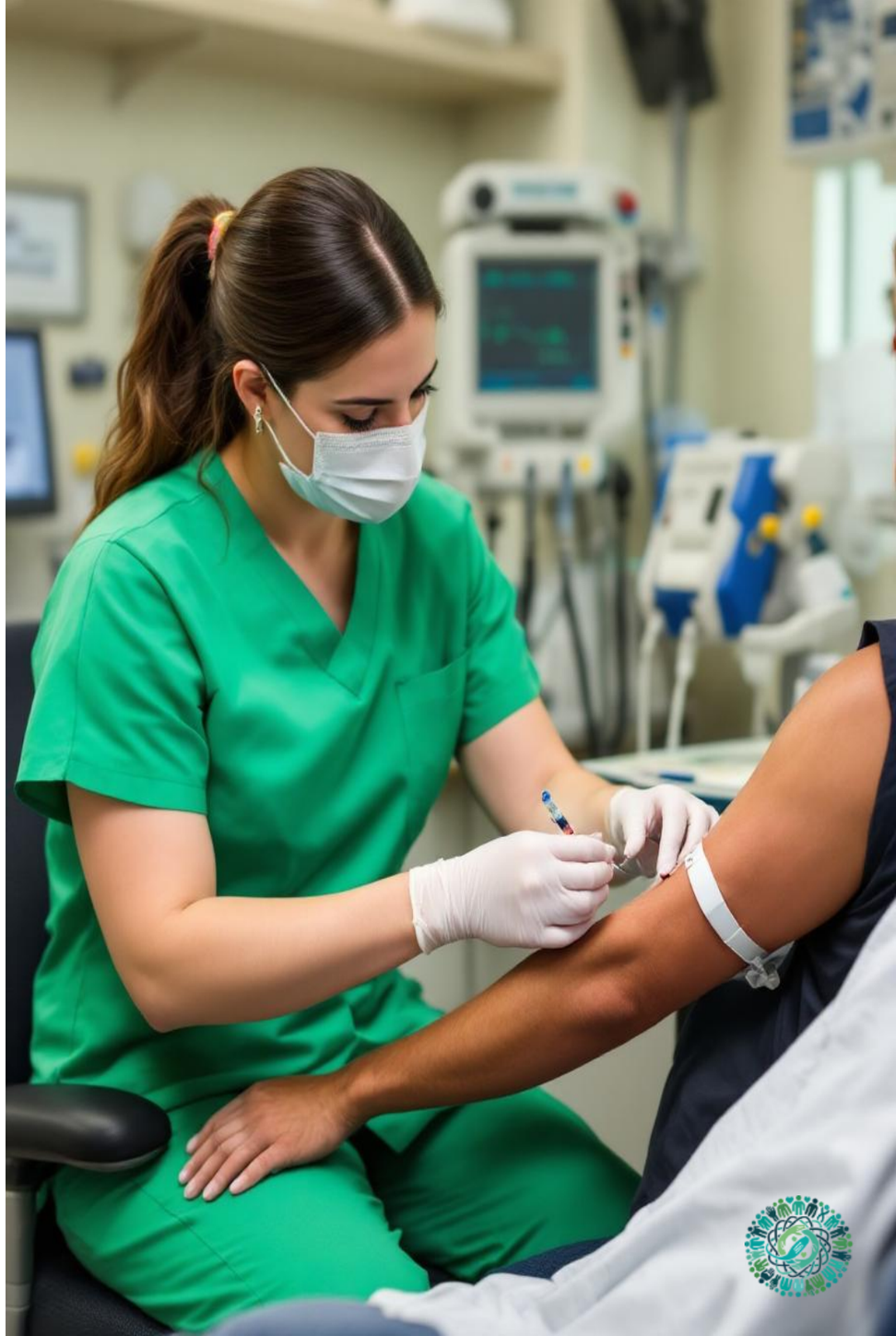
You sign a form after understanding and agreeing to participate.

Regular Monitoring

Expect check-ups, tests, and questionnaires to track your progress.

Ongoing Support

The research team remains available to address concerns.



Finding a Clinical Trial

Online Resources

Reputable websites and clinical trial registries, including Clinicaltrials.gov, CenterWatch, The NHS website and The WHO ICTRP. Some Patient Organisations and charities also promote trials.

Healthcare Providers

Your doctor can suggest appropriate trials and make referrals.

Local Institutions

Nearby hospitals, clinics, and universities often conduct clinical research.

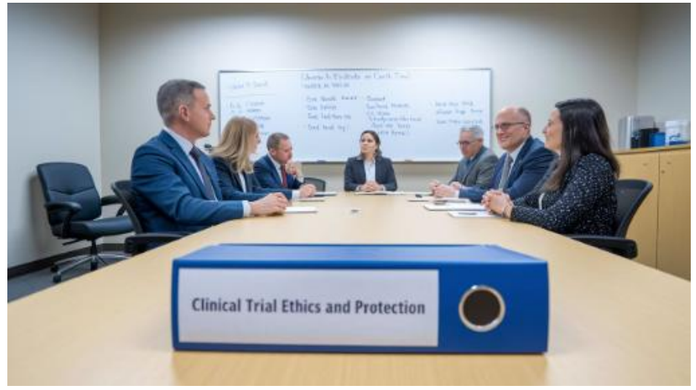
Benefits & Risks

Benefits

- Access to new treatments.
- Contributing to medical advances.
- Extra medical attention.
- Closer monitoring and deeper understanding of one's condition.

Risks

- Possible side effects.
- Treatment might not work.
- Additional commitments of time, appointments and tests.
- May interfere with family or work life.



Protections

- Ethical review boards.
- Informed consent process.
- Right to withdraw anytime.
- On-going monitoring and safeguards.
- Regulatory standards to protect rights, safety and privacy.

Useful Key Terms

Placebo	Inactive treatment used as a comparison control.
Randomized	Participants assigned, by chance, to different treatment groups, e.g. treatment or placebo.
Blinded/Blinding	Neither participants nor researchers know which treatment is given.
Informed Consent	Voluntary agreement after understanding all risks and benefits.
Protocol	The detailed plan, instruction manual, for conducting the clinical trial.
Control Group	A group of participants who receive a placebo to enable a comparison to the treatment group.
Intervention	The treatment, procedure or action being studied.
Adverse Event	Any undesirable experience or side effect associated with the use of a medical treatment.
Endpoint	The main outcome of the study, to see if the treatment is working e.g., reduced blood pressure

Thank you

We hope you found this information helpful

Any feedback on this or any of our other documents please let us know:
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