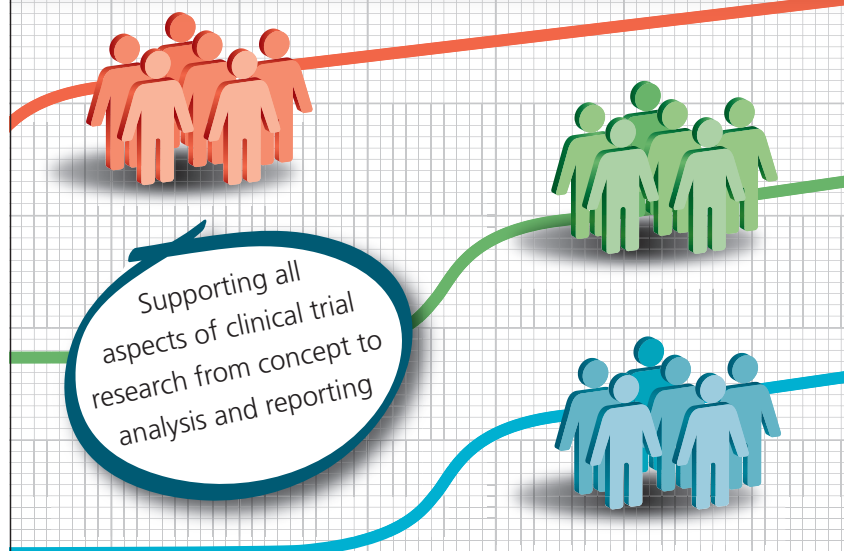




Leicester Clinical Trials Unit



Clinical trials of drugs, devices and other interventions

Trial Development

- Study design and sample size calculation
- Input to funding application

Trial and Data Management

- Case report form (CRF) design
- Database design, validation and management
- Randomisation service
- Multi-site trial coordination
- Oversight of GCP and regulatory compliance

Analysis and Reporting

- Writing of statistical analysis plans
- Reporting to IDMC or DSMB
- Statistical analysis and reporting
- Support for presentations and publications

