

INTRODUCTION TO CLINICAL RESEARCH AND GOOD CLINICAL PRACTICE (GCP) Monday 2nd October 2017 Newman Study, RCSI 123 St Stephens Green

RCSI DEVELOPING HEALTHCARE LEADERS WHO MAKE A DIFFERENCE WORLDWIDE

Agenda

| 09:00 | Introduction |
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| 09.15 | Introduction to Drug Development and Clinical Research |
| | Drug Development |
| | Clinical Trial Phases |
| 10:15 | Research Governance |
| | Background |
| | Legislation & Guidelines |
| | Workshop 1 |
| 11:00 | Coffee Break |
| 11:30 | Principles of Good Clinical Practice |
| 12:00 | Investigator Responsibilities, |
| | Including Workshop 2 |
| 13:00 | Lunch Break |
| 13:45 | Investigator Responsibilities, |
| | Including Workshop 3 |
| 15.15 | Essential Documents and GCP Inspections |
| 15:45 | GCP Quiz |
| 16:00 | Concluding Comments |

This programme is applicable to clinical research team members who have not previously attended GCP training, or not within the past 2 years. Eligible for 6 CPD Credits (NMBI), applicable to all disciplines.

"This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors."