

| SOP#<br>version                       | Title   | Effective Date<br>(dd-Mon-yyyy) |
|---------------------------------------|---|---------------------------------|
| <b>N2 SOPs (001 – 019, 023 - 025)</b> |   |                                 |
| 001_09                                | Standard Operating Procedure (SOP) Administrative Management by Network of Networks | 15-May-2021                     |
| 002_09                                | Research Team Roles and Responsibilities  | 15-May-2021                     |
| 003_09                                | Research Team Training  | 15-May-2021                     |
| 004_09                                | Clinical Research Protocol Feasibility and Site Selection                           | 15-May-2021                     |
| 005_09                                | Study Initiation/Activation   | 15-May-2021                     |
| 006_09                                | Informed Consent Forms  | 15-May-2021                     |
| 007_09                                | Research Ethics Board: Submissions and Ongoing Communication                        | 15-May-2021                     |
| 008_09                                | Informed Consent Process  | 15-May-2021                     |
| 009_09                                | Subject Recruitment and Screening   | 15-May-2021                     |
| 010_09                                | Management of Investigational Products  | 15-May-2021                     |
| 011_09                                | Management of Biological Specimens  | 15-May-2021                     |
| 012_09                                | Serious Adverse Drug Reaction Reporting in Clinical Trials                          | 15-May-2021                     |
| 013_09                                | Study Monitoring and Communication  | 15-May-2021                     |
| 014_09                                | Clinical Data Management  | 15-May-2021                     |
| 015_09                                | Investigator Study Files and Essential Documents                                    | 15-May-2021                     |
| 016_09                                | Study Close-Out   | 15-May-2021                     |
| 017_09                                | Audits and Inspections  | 15-May-2021                     |
| 018_09                                | Clinical Trial Application (Drugs)  | 15-May-2021                     |
| 019_09                                | Confidentiality and Privacy   | 15-May-2021                     |
| 020_01                                | <i>CRF Design; this SOP was re-numbered to 100_02 in May 2011</i>                   |                                 |
| 021_01                                | <i>Study Analysis and Reporting; this SOP was re-numbered to 101_02 in May 2011</i> |                                 |
| 022_01                                | <i>Protocol Development; this SOP was re-numbered to 102_02 in May 2011</i>         |                                 |
| 023_05                                | Clinical Trial Application (Natural Health Products)                                | 15-May-2021                     |

## SOP Table of Contents

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|-------------------------|---|---|
| 024_05                  | Investigational Testing Authorization (ITA) for Medical Devices (non-IVDD) and Manufacturer/Sponsor Obligations | 15-May-2021                             |
| 025_05                  | Equipment Calibration and Maintenance   | 15-May-2021                             |

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|---|---|---|
| <b>Investigator-Initiated (IIS) SOPs (100 -109)</b> |   |   |
| 100_07  | CRF Design                              | 15-May-2021                             |
| 101_07  | Study Analysis and Reporting            | 15-May-2021                             |
| 102_07  | Protocol Development                    | 15-May-2021                             |
| 103_06  | Data Management Plan                    | 15-May-2021                             |
| 104_06  | Database Set-up                         | 15-May-2021                             |
| 105_06  | Database Maintenance and Management     | 15-May-2021                             |
| 106_06  | File Transfer                           | 15-May-2021                             |
| 107_06  | Database Lock and Archiving             | 15-May-2021                             |
| 108_06  | System Set-up, Maintenance and Security | 15-May-2021                             |
| 109_06  | System Backup and Recovery Planning     | 15-May-2021                             |

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|---|-------------------|---|
| <b>Other Documents (update as required)</b> |                   |   |
| N/A   | Glossary of Terms | 15-May-2021                             |