Title: Glossary of Definitions			Page 1 of 32
Document No: CRF.SPN.000	Version No: Version 1	Effective Date: 1st Oct 2020	Supersedes Version: N/A

Prepared by:

Signature: Norah Cassidy Date: 29 Sep 2020

Print Name: Norah Cassidy

Title: Sponsor Project and Quality Manager

Reviewed by:

Signature: Date: 30 Sep 2020

Print Name: Greg Purcell

Title: Data Manager and Quality Officer

Approved by:

Signature: Date: Sep 30, 2020

Print Name: Sinead Callinan

Title: Head of Clinical Sponsorship Oversight

1. Definitions

Term	Abb.	Definition
Adverse Drug Reaction	ADR	In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).
Adverse Event	AE	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

ALCOA-C	ALCOA-C	ALCOA-C is a guiding principle for good documentation standards which identifies the following critical principles for source documents in research A: Attributable, L: Legible, C: Contemporaneous O: Original, A: Accurate and C: Complete
Annual Safety Report	ASR	The Annual Safety Report is a summary of the current status of knowledge and describes the identified and potential risks of active substances / medicinal products during clinical trials.
Applicable regulatory requirement(s)		Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.
Approval (in relation to institutional review boards)		The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.
Audit		A systematic and independent examination of study related activities and documents to determine whether the evaluated study related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, Sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Audit Certificate		A declaration of confirmation by the auditor that an audit has taken place.
Auditee		The organisation being audited.
Auditor		A person with the competence to conduct an audit.
Audit Report		A written evaluation by the Sponsor's auditor of the results of the audit.
Audit Trail		Documentation that allows reconstruction of the course of events.
Backup		The entire system that supports the process of backing up copies of data, so that these copies may be used to restore the original after data loss. Organizing the storage space and media required and managing the backup process can be complex, and corporate backup systems normally include a central module that

		supports this management, identifying the data to be backed up and the method to be used, logging activities and their outcome, managing media etc. This central system interacts with 'backup clients' installed on each machine that is backed up, which respond to the instructions of the central system and which generate the file copies, produce local logs etc.
Batch		A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.
Blinding / Unblinding		A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s). For Unblinding Procedures refer to ICH E6, 4.7 and 5.13.4
Case Report Form	CRF	A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the Sponsor on each study subject.
Centralised monitoring		Remote evaluation of accumulating data, performed in a timely manner, supported by appropriately qualified and trained persons (e.g., data managers, biostatisticians).
Certified Copy		A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.
Clinical Evaluation		The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer
Clinical Investigation		'Clinical Investigation' means any systematic investigation in one or more human subjects,

		undertaken to assess the safety or performance of a medical device.
Clinical Investigation Plan	CIP	Document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation in accordance with EN ISO 14155-2: 2009
Clinical Performance		The ability of a medical device to achieve its intended purpose as claimed by the manufacturer.
Clinical Research Associate	CRA	See also "monitor"
Clinical Research Governance Group	CRGG	The Clinical Research Governance Group is established to provide oversight of Trinity College Dublin functions as a Sponsor of Clinical Trials in accordance with guidelines for Good Clinical Practice (GCP) and all applicable legislation.
Clinical Safety		As related to medical devices, is the absence of unacceptable clinical risks, when using the device according to the manufacturer's Instructions for Use
Clinical Study / Clinical Trial	CSR / CTR	A 'clinical study' is defined as any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients. It includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EC) The terms clinical trial and clinical study are synonymous.
Clinical Trial Authorisation	CTA	Written notification from the regulatory authority giving authorisation to proceed to initiate a regulated clinical trial
Clinical Trial of an Investigational Medicinal Product	CTIMP	A CTIMP in human subjects is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Clinical Trials Ordinance	ClinO	Ordinance on Clinical Trials in Human Research of 20 September 2013 (www.admin.ch/opc/en/classified-compilation/20121176/index.html) Comment: Used in the Risk based monitoring system of the Swiss Clinical Trial Organisation
Clinical trial/study report		A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).
Close-out visit	COV	Monitoring visit conducted to ensure the site is ready to cease all trial activities, the database can be locked and files can be archived.
Coding		In clinical trials, the process of assigning data to categories for analysis. NOTE: Adverse events, for example, may be coded using MedDRA.
Committee for Medicinal Products for Human Use	CHMP	The Committee for Medicinal Products for Human Use (CHMP) is the European Medicines Agency's (EMA) committee responsible for human medicines. The CHMP replaced the former Committee for Proprietary Medicinal Products (CPMP) in May 2004.
Comparator (Product)		An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.
Competent Authority	CA	A competent authority is the organisation with the authority to act on behalf of the government to ensure that all medicinal products and medical devices meet the essential requirements laid down in the Federal Law prior to marketing authorisation.
Compliance (in relation to trials)		Adherence to all the trial-related requirements, Good Clinical Practice (GCP)requirements, and the applicable regulatory requirements.
Confidential Disclosure Agreement	CDA	A CDA is a legal document that ensures confidentiality of proprietary information that a Sponsor gives to the principle investigator. A signed, study specific CDA may be required before a Sponsor will provide its

		proprietary information, such as the study protocol, to an Investigator.
Confidentiality		Prevention of disclosure, to other than authorized individuals, of a Sponsor's proprietary information or of a subject's identity.
Conflict of Interest	COI	One potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the Sponsor of the covered study. It requires applicants looking to conduct a clinical trial to submit a list of all investigators who will be working on the trial paired with a certification that either no financial arrangements exist that would cause a problem, or explaining the nature and extent of those holdings and why they do not pose a problem to the conduct of the trial.
Conformity Assessment		The systematic examination of evidence generated and procedures undertaken by the manufacturer, according to Article 9 of directive 90/385/EEC and Article 11 of directive 93/42/EEC, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Requirements according to Annex 1 of directive 90/385/EEC and Annex I of directive 93/42/EEC.
Contract		A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.
Contract Research Organisation	CRO	A person or an organisation (commercial, academic, or other) contracted by the Sponsor to perform one or more of a Sponsor's trial-related duties and functions.
Coordinating committee		A committee that a Sponsor may organize to coordinate the conduct of a multicentre trial.

Coordinating Investigator	CI	An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicentre trial.
Corrective and Preventative Action	CAPA	CAPA is the abbreviation for corrective action and preventive action. These two aspects of CAPA have traditionally been connected but are ideally are only distantly related. Here is the main difference between the two: Corrective Action: Elimination of the cause or causes of an existing nonconformity or undesirable situation in order to prevent recurrence. Preventive Action: Identification and elimination of the cause(s) of potential nonconformities in order to prevent occurrence.
Council for International Organizations of Medical Sciences	CIOMS	The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organisation established jointly by WHO and UNESCO in 1949. "The main objectives of CIOMS are: to facilitate and promote international activities in the field of biomedical sciences and to serve the scientific interests of the international biomedical community in general." Note: The CIOMS Form I, has been a widely accepted standard for expedited adverse event reporting.
Database Lock		A database is locked when an organisation's pre-specified database closure procedures have been completed or otherwise approved. At the time of lock, to the best of the Sponsor's knowledge, the data is complete, meets pre-specified acceptance criterion and is acceptable for analysis. Access granted to database users has been restricted to "read-only."
Data Management	DM	Tasks associated with the entry, transfer, and/or preparation of source data and derived items for entry into a clinical trial database. NOTE: Data management could include database creation, data entry, review, coding, data editing, data QC, locking, or archiving; it typically does not include source data capture.

Data Management Plan	DMP	The DMP should document the processes and procedures employed to promote consistent, efficient and effective data management practices. It should document the relevant convention of a particular study, before data collection begins. Comment: For details regarding content and structure refer to the relevant chapter Data Management Plan in GCDMP
Data Protection Officer	DPO	A data protection officer (DPO) is a role required by the General Data Protection Regulation (GDPR). Data protection officers are responsible for overseeing an organisations data protection strategy and its implementation to ensure compliance with GDPR requirements.
Data Safety Monitoring Board	DSMB	A DSMB is a group of independent individuals, external to the trial, who are experts in relevant areas. They review the accumulated data from one or more ongoing clinical trials on a regular basis and advise the Sponsor about: • The continued safety of the trial participants. • The continued validity of the trial. • The continued scientific merit of the trial. Synonyms: (Independent)Data Monitoring Committee (IDMC/DMC)
Developmental International Birth date	DIBD	Date of first approval (or authorisation) for conducting an interventional clinical trial in any country" (ICH E2F)
Development Safety Update Report	DSUR	The DSUR should provide safety information from all on-going clinical studies that the Sponsor is conducting or has completed during the review period including: – clinical studies conducted using an investigational drug whether with or without a marketing approval, i.e., human pharmacology, therapeutic exploratory and therapeutic confirmatory studies (Phase I – III) – clinical studies conducted using marketed drugs in approved indications, i.e., therapeutic use studies (Phase IV) – other therapeutic use of an investigational drug

		– comparability studies conducted to support changes in the manufacturing process of medicinal products. The DSUR is intended to be a common standard for periodic reporting on drugs under development (including marketed drugs that are under further study) among the ICH regions.
Device intended for clinical investigation		Any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Sections 2.1 of Annex 7 of directive 90/385/EEC and section 2.1 of Annex X of directive 93/42/EEC in an adequate human clinical environment.
Direct Access		Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, Sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and Sponsor's proprietary information.
Documentation		All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms), that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.
Document Author		An individual who is a subject matter expert or an individual who actually performs the task described in the procedure.
Electronic Case Report Form	eCRF	An auditable electronic record designed to record information required by the clinical trial protocol to be reported to the Sponsor on each trial subject.
Electronic Remote Data Capture	eRDC	The data entry direct from sites. In most eRDC systems access for data entry will be via a web browser.
Encrypted Transmission		Transmission over the internet can be encrypted at various levels. In this context encryption needs to apply to the whole of the data interchange, and not (as is sometimes the case) just to the initial certificate. The generally recommended encryption level is the 128 bit

		Advanced Encryption Standard (AES-128), earlier standards having now been shown to be insecure. File transfer should therefore have to use data encrypted to at least this standard, as should remote access systems, e.g. VPN and Citrix.
End Of Trial Notification		The end of a trial, whether it ends earlier than planned or according to the protocol, must be notified to the HPRA using the EU Declaration of the End of Trial form. If a trial ends in Ireland before it has ended globally, the Sponsor should complete this form to notify the HPRA of the local or national end of trial.
Endpoint		Indicators measured or determined to assess the objectives of a clinical investigation, prospectively specified in the clinical investigation plan. (EN ISO 14155_2:2009, modified)
Essential Documents		Essential Documents are those documents, which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, Sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Essential documents for the trial should be supplemented of may be reduced where justified (in advance of trial initiation) based on the importance and relevance of the specific documents to the trial.
Eudravigilance Clinical Trial Module	EVCTM	The EudraVigilance Clinical Trial Module to facilitate the electronic reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) as required by Directive 2001/20/EC
European Economic Area	EEA	The European Economic Area, abbreviated as EEA, consists of the Member States of the European Union (EU) and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway; excluding Switzerland)
European Medicines Agency	EMA	The European Medicines Agency (EMA) is a decentralised body of the European Union with headquarters in London. Its main responsibility is the

		protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.
European Database on Medical Devices	EUDAMED	EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.
European Union	EU	The European Union is a unique economic and political union between 27 EU countries that together cover much of the continent.
European Union Drug Regulating Authorities Clinical Trials	EUDRACT	EudraCT (European Union Drug Regulating Authorities Clinical Trials Database) is the European database for all interventional clinical trials on medicinal products authorized in the European Union (EEA) and outside the EU/EEA if they are part of a Paediatric Investigation Plan (PIP) from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC. Protocol and results information on interventional clinical trials are made publicly available through the European Union Clinical Trials Register since September 2011.
Feasibility visit		A pre study visit conducted to assess the feasibility and suitability of a site for a trial.
Financial Disclosure	FD	Financial Disclosure by Clinical Investigators requires the Sponsor of a marketing application for any drug product, including any biological product, or any device to submit certain information concerning the compensation to, and financial interests of, clinical investigators conducting certain clinical studies. Requires the Sponsor to certify to the absence of certain financial interests of clinical investigators and/or disclose those financial interests.
For-cause monitoring visit		Monitoring visit conducted outside of the TMP due to concerns raised about the conduct of the trial at the site.
Good Clinical Practice	GCP	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, 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.
Good Manufacturing Practice	GMP	EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use.
Head of Clinical Sponsorship Oversight	HCSO	The HCSO acts as the Sponsor Officer for Trinity College.
Health Products Regulatory Agency	HPRA	The Regulatory Authority or "competent authority" in Ireland. A body having the power to regulate whose role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. In the ICH GCP guideline, the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29).
Health Research Consent Declaration Committee	HRCDC	The Health Research Consent Declaration Committee (HRCDC) was established in Ireland as part of the Health Research Regulations made under the Data Protection Act, 2018.
Health Research Regulations	HRR	The suitable and specific measures for data processing provided for in Section 36 of the draft Data Protection Act 2018 are given further and more specific effect through the Health Research Regulations 2018 (formally titled Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018). The Health Research Regulations 2018: • Outline the mandatory suitable and specific measures for the processing of personal data for the purposes of health research (Regulation 3(1)) • provide a definition of health research for the purposes of the regulation (Regulation 3(2)) • provide for the possibility of applying for a consent declaration for new research (Regulation 5) • provide for transitional arrangements in respect of the granting of consent declarations for

		health research that is already underway (Regulation 6) • provide for the establishment and operation of a committee of persons to make decisions on applications for consent declarations, including an appeals process (Regulation 7-13 and Schedule) • include a number of miscellaneous provisions (Regulations 14-16)
Impartial Witness		A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the Informed Consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the Informed Consent Form and any other written information supplied to the subject.
Independent Data-Monitoring Committee (IDMC) (data and safety monitoring board, monitoring committee, data monitoring committee)	IDMC	An independent data-monitoring committee that may be established by the Sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the Sponsor whether to continue, modify, or stop a trial.
Independent Ethics Committee	IEC	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but

		should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.
Individual Case Safety Report	ICSR	Individual Case Safety Report (ICSR) captures information needed to support reporting of adverse events, product problems and consumer complaints associated with the use of regulated products.
Informed Consent	IC	A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
Informed Consent Form	ICF	Informed consent is documented by means of a written, signed and dated Informed Consent Form.
Inspection		The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical study and that may be located at the site of the study, at the Sponsor's and/or contract research organisation's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).
Institution (medical)		Any public or private entity or agency or medical or dental facility where clinical trials are conducted.
Institutional Review Board	IRB	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Intellectual Property		Intellectual property rights are the legally recognised exclusive rights to creations of the mind. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as discoveries,

		inventions, designs etc. Common types of intellectual property rights include copyright, trademarks, patents, industrial design rights, trade dress, and in some jurisdictions trade secrets.
Interim Analysis		Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial.
Interim Clinical Trial / Study Report		A report of intermediate results and their evaluation based on analyses performed during the course of a trial.
Interim monitoring visit	IMV	Monitoring visit conducted on a regular basis as per the TMP to ensure activities at site are being conducted according to the protocol, GCP and applicable regulatory requirements and to conduct source data verification.
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The work carried out by ICH under the Efficacy Guidelines is concerned with the design, conduct, safety and reporting of clinical trials. NOTE: Following guidelines are of most importance for the GGOP. – ICH E2A: Clinical safety data management. Definitions and Standards for Expedited Reporting I – ICH E2C (R2): Periodic Safety Update Reports for Marketed Drugs (PSUR) – ICH E2F: Development Safety Update Report (DSUR) – ICH E6: Guideline for Good Clinical Practice E6 (R2) – ICH E8: General Considerations for Clinical Trials
International Organization for Standardization	ISO	ISO is the world's largest developer and publisher of International Standards.
Investigational (Medicinal) product	I(M)P	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical

		trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Investigational Medicinal Product Dossier	IMPD	The Investigational Medicinal Product Dossier is required for approval of clinical trials by the competent authorities in the EU. It should provide information on quality data, non-clinical pharmacology and toxicology data, clinical trial and previous human experience data, and overall risk and benefit assessments for the test product, reference product and placebo.
Investigator		A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Sub Investigator.
Investigator brochure	IB	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects
Investigator Initiated Trials	IIT	Also referred to as an investigator-initiated study (IIS), an IIT is a clinical trial in which the investigator conceives the research, develops the protocol and serves as Sponsor investigator. The Sponsor investigator initiates and conducts a clinical trial – alone or with a team. It's under the Sponsor investigator's immediate direction that the investigational product is administrated, dispensed to or used by a subject. As the name implies, the obligations of a Sponsor investigator include both those of a Sponsor and those of an investigator: both creating and coordinating the study and conducting it.
Investigator Site File	ISF	A standard filing system which contains all essential documents held by the Principal Investigator(s) conducting a trial which individually and collectively permit the evaluation of the conduct of the trial and the quality of the data produced.

Legally Acceptable Representative	LAR	An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Management		Coordinated activities to direct and control an organisation Management can include establishing policies and objectives, and processes to achieve these objectives.
Management System	MS	Set of interrelated or interacting elements of an organisation to establish policies and objectives, and processes to achieve those objectives.
Marketing Authorisation	MA	An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorized on is based (e.g. "The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorisation, and the period of validity of the authorisation. Once a product has been given marketing authorisation, it is included on a list of authorised products – the register – and is often said to be "registered" or to "have registration".
Marketing Authorisation Holder	MHA	The person or company in whose name the marketing authorisation has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorisation. The authorisation holder must be subject to legislation in the country that issued the marketing authorisation, which normally means being physically located in the country.

Medical Device		Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: – Diagnosis, prevention, monitoring, treatment or alleviation of disease, – Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, – Investigation, replacement or modification of the anatomy or of a physiological process, – Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Medical Dictionary for Regulatory Activities	MedDRA	In the late 1990s, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific authorisation medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. Comment: MedDRA is used by regulatory authorities and the regulated biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation. In addition, it is the AE classification dictionary endorsed by the ICH for safety reporting
Medicinal Product		(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological,

		immunological or metabolic action, or to making a medical diagnosis.
Monitor		The Monitor is appointed by the Sponsor and verifies that the rights and well-being of human subjects are protected, the reported trial data are accurate, complete, and verifiable from source documents, and the conduct of the trial is in compliance with the currently approved protocol/ amendment(s), with GCP, and with the applicable legal and regulatory requirement(s).
Monitoring		The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Monitoring Plan	MP	A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial.
Monitoring report		A written report from the monitor to the Sponsor after each site visit and/or other trial-related communication according to the Sponsor's SOPs
Multicentre trial		A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
Nonclinical study		Biomedical studies not performed on human subjects.
Non-interventional Study		A prospective observational study where medicinal product(s) are prescribed in the usual manner in accordance with the terms of the marketing authorization or where the patient's therapy and management is in accordance with the accepted standard of care. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study.

		The study may involve the collection of biological samples and the use of questionnaires or interviews to better understand the mechanisms of a disorder but no additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.
Non-Investigational Medicinal Product		Products which are not the object of investigation (i.e. other than the tested product, placebo or active comparator) may be supplied to subjects participating in a trial and used in accordance with the protocol. For instance, some clinical trial protocols require the use of medicinal products such as support or rescue/escape medication for preventive, diagnostic or therapeutic reasons and/or to ensure that adequate medical care is provided for the subject. They may also be used in accordance with the protocol to induce a physiological response.
Non-regulated Clinical Trial		A non-regulated clinical trial is a clinical trial that does not fall within a specific legislative framework.
Note To FIle	NTF	A Note to File is written to identify a discrepancy in the conduct or documentation of the Clinical Study. It notes the root cause or rationale for the identified discrepancy and identifies the corrective action taken and resolutions (as applicable).
Opinion (in relation to independent ethics committee)		The judgement and/or the advice provided by an Independent Ethics Committee (IEC).
Organisation		Person or group of people who have their own functions with responsibilities, authorities and relationships to achieve their objectives.
Participant		An individual or patient whom consents to take part in a clinical trial
Patient Information Leaflet and Informed consent form	PIL-ICF	Study information text(s) or any written information on the proposed research, which is handed out to the potential study subject, explaining all relevant information concerning the study in an easily understandable layman's language. Comment: See also ICH E6, 4.8.5 and 4.8.6

Periodic Safety Update Report	PSUR	Periodic Safety Update Reports for Marketed Drugs. A report, which contains a concise critical summary of the safety profile of the drug under study, as well as the safety issues that have arisen during the reporting period.
Pharmacovigilance	PV	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The European Medicines Agency (EMA) coordinates the European Union (EU) pharmacovigilance system and operates services and processes to support pharmacovigilance in the EU.
Principal Investigator	PI	See Investigator.
Procedure		Specified way to carry out an activity or a process. Procedures can be documented or not.
Process		Set of interrelated or interacting activities that use inputs to deliver an intended result.
Product		Output of an authorisation with at least one activity necessarily performed between the authorisation and the customer.
Product Specification Files	PSF	A reference file containing, or referring to files containing, all the information necessary to draft the detailed written instructions on processing, packaging, quality control testing, batch release and shipping of an investigational medicinal product.
Project		Unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.
Protocol		A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

Protocol amendment		A written description of a change(s) to or formal clarification of a protocol.
Protocol ID		A unique Sponsor reference identifier assigned to a clinical trial using the naming/numbering convention as determined by the QMS.
Qualified Person	QP	A Qualified Person or 'QP', is defined within Irish law applicable to human medicinal products as 'a person with the qualifications and experience specified in Schedule 5 and named in the manufacturer's authorisation as being responsible at the manufacturer's premises for the functions set out in Regulation 13(3)'. A similar definition is provided for in Irish law relevant to veterinary medicinal products.
Quality and Regulatory Affairs Manager	QRAM	Quality and Regulatory Affairs Manager for the Clinical Research Facility, St James's Hospital. Responsible for the site quality and regulatory affairs.
Quality Assurance	QA	All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).
Quality Control	QC	The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.
Quality Management		Management with regard to quality. Comment: QM can include establishing quality policy policies and quality objectives, and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement.
Quality Management System	QMS	A quality management system (QMS) is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization (i.e., areas that can impact the organization's ability to meet customer requirements).
Query		A request for clarification on a data item collected for a clinical trial; specifically a request from a Sponsor or Sponsor's representative to an investigator to resolve

		an error or inconsistency discovered during data review
Randomization		The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Randomized Controlled Trial	RCT	A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention. One group (the experimental group) has the intervention being tested, the other (the comparison or control group) has an alternative intervention, a dummy intervention (placebo) or no intervention at all. The groups are followed up to see how effective the experimental intervention was. Outcomes are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.
Record		Document stating results achieved or providing evidence of activities performed. Records can be used, for example, to authorisation traceability and to provide evidence of verification, preventive action and corrective action. Generally, records need not be under revision control.
Reference Safety Information	RSI	The RSI is a list of expected serious adverse reactions, which are classified using Preferred Terms (PTs) according to the Medical Dictionary for Regulatory Activities (MedDRA). The primary purpose of the RSI when used in clinical trials is to serve as the basis for expectedness assessments of suspected serious adverse reactions for expedited reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) and annual safety reporting. Thus the RSI section of the IB should only contain expected Serious Adverse Reactions (expected SARs) to the Investigational Medicinal Product(s).
Regulated Clinical Trial		A regulated clinical trial is a clinical trial that falls under the remit of the Competent Authority, in Ireland the Health Product Regulation Authority (HPRA) i.e. they need HPRA approval. These trials typically involve an

		Investigational Medicinal Product (IMP) or Medical Device that falls under the IMP regulatory framework (SI 190/2004) which makes compliance with a specific set of Good Clinical Practice 'guidelines' (ICH GCP) and the EU Clinical Trial Regulation EU#536/2014 or the EU Medical Device Regulation 2017/745 a legal requirement for study conduct.
Regulatory authorities		Bodies having the power to regulate. In the ICH GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29). These bodies are sometimes referred to as competent authorities.
Research Ethics Committee	REC	A Research Ethics Committee (REC) is the acknowledged international best practice structure for overseeing the conduct of ethical standards in healthcare research.
Rich Text Format	RTF	RTF is a file format standardized by Microsoft for creating formatted text files. Unlike a basic text file, an RTF file can include information such as text style, size, and color. It is a universal format, meaning it can be read by nearly all word processors.
Risk-based monitoring	RBM	The process of ensuring the quality of the conduct of a trial by identifying, assessing, monitoring and mitigating risks that could affect the safety and/or quality of the trial.
Risk Management		The systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk (EN ISO 14971:2009) for medical devices.
Safety Signals		Information that arises from one or multiple sources (including observations or experiments), which suggests a new, potentially causal association, or a new aspect of a known association between an intervention [e.g., administration of a medicine]and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

Serious Adverse Event, Serious Adverse Reaction or Serious Adverse Drug Reaction	SAE, SAR, Serious ADR	Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect In addition, important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed above should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation, or development of drug dependency or drug abuse.
Service		Output or an organisation with at least one activity necessarily performed between the organisation and the customer.
Service Level Agreement	SLA	In contrast to a contract, an SLA would focus only on the performance metrics and service quality agreed to by both parties, and may be used as a measurement tool as part of the contract. Comment: The rationale for having a *separate* SLA document is that the SLA can be revised without having to revise the contract. The contract can just refer to the agreed SLA. The contract might then last for 2 years but the SLA may be reviewed quarterly, for example. This reduces the administrative burden of reviewing the contract too frequently
Severe Adverse Device Effects	SADES	adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event
Site initiation visit	SIV	Monitoring visit conducted to ensure all required training has been completed by site staff, all required resources are on site, tasks and responsibilities have been appropriately delegated and the site is ready to

		receive their Sponsor green light approval and to commence screening and recruitment.
Source data		All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).
Source Data Verification	SDV	The process of ensuring that data that have been derived from source data accurately represent the source data.
Source documents		Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
Sponsor		An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor-Investigator		An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a Sponsor-investigator include both those of a Sponsor and those of an investigator.
Sponsor Project and Quality Manager	SPQM	An appropriately qualified individual, who supervises on behalf of the Sponsor the overall conduct of the study, handles the data, verifies the data, conducts the statistical analyses, and prepares the study report.
Sponsor Representative	SR	The institutional role that is intended to help the Institution ensure any risk associated with clinical

		research is understood, accepted and adequately managed. He/she is the institutional point of contact for Sponsorship applications and approvals.
Standard Operating Procedures (SOPs)		Written procedures followed in order to achieve uniform performance of a specific company practice or discipline. When implemented, they provide the standard process to be followed for conducting the specific practice and/or discipline to ensure quality.
Statistical Analysis Plan	SAP	A statistical analysis plan is a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.
Statutory Instrument	SI	Under the Statutory Instruments Act 1947 a statutory instrument is defined as being "an order, regulation, rule, scheme or bye-law made in exercise of a power conferred by statute.
Study Nurse		Study nurse or research nurse is a nurse who co-supervises clinical studies at hospitals, doctor's offices or the pharmaceutical industry. The study nurse is responsible for the protocol defined conduct of the study
Sub Investigator		Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.
Subject/trial subject		An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
Subject identification code		A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.
Summary of Product Characteristics	SmPC	SmPCs are a key part of the marketing authorisation of all medicines authorised in the European Union and the basis of information for healthcare professionals

		on how to use a medicine safely and effectively. They are kept updated throughout the lifecycle of a medicine as new efficacy or safety data emerge. SmPCs are also the basis for the preparation of package leaflets, so are important documents in enabling information on medicines to reach patients.
Suspected Unexpected Serious Adverse Reaction	SUSAR	SUSARs are Adverse Drug Reactions that are suspected to be both serious and unexpected. See also SAE and Unexpected Adverse Drug Reaction
Swiss Clinical Trial Organisation	SCTO	The SCTO helps to optimize the framework conditions for clinical research and to establish the necessary (inter) national contacts. In addition, they strengthen the next generation with the help of a training program that specifically addresses the needs of the next generation. The SCTO also enables access to research infrastructures in Europe, for example via ECRIN (European Clinical Research Infrastructures Network), which offers researchers comprehensive management and advisory services for multicenter, multinational studies.
Training		The acquisition of knowledge, abilities, competencies and/or practical skills as a result of teaching by persons qualified by education and/or experience in the specific required competencies. Training can be provided in the form of courses, tutorials, online courses or written instructions.
Trial Management Group	TMG	Those individuals responsible for the day-to-day management of the trial, such as the PI, statistician, trial manager, research nurse, data manager whose collective role is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.
Trial Master File	TMF	A Trial Master File contains the minimal set of Essential Documents as defined in GCP Art. 8.2 - 8.4. It should be established at the beginning of the trial, both at the investigator/institution's site (Investigator Site File) and at the Sponsor's office (Trial Master File/Study Master File).

Trial site		The location(s) where trial-related activities are actually conducted.
Trial Steering Committee	TSC	The role of the Trial Steering Committee (TSC) is to provide the overall supervision of the trial. Ideally, the TSC should include members who are independent of the investigators, their employing organisations, funders and Sponsors.
Unexpected adverse drug reaction		An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).
Urgent Safety Measure	USM	A USM is any action, which is not defined in the protocol, required to be taken by the Sponsor and/or Investigator (s) to protect study subjects from any immediate hazard to their health and/or safety. A USM can be put into place with immediate effect, without needing to gain prior authorization by the REC or HPRA (for CTIMPS).
Validation of Computerized Systems		A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results.
Vulnerable subjects		Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the

		pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
Well-being (of the trial subjects)		The physical and mental integrity of the subjects participating in a clinical trial.
Wellcome Trust, HRB Clinical Research Facility, St James's Hospital	CRF-SJH	Wellcome Trust, HRB Clinical Research Facility, St James's Hospital
World Health Organisation	WHO	WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

6. References

a) EMA/CHMP/ICH/135/1995 Guideline for Good Clinical Practice E6 (R2)
b) ISO 9001:2015
c) SIO 14155:2020
d) Commission Directive 2005/28/EC
e) SI190/2004 as amended
f) EU Clinical Trials Register
g) FDA
h) CIOMS
i) World Medical Association

j) ICH E2F
k) European Commission
l) DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018
m) Swiss Clinical Trial Organisation

7. Revision History

Version	Description of Changes	Effective Date
1	New Document	1st October 2020

CRF.SPN.000- V1 Glossary of Definitions (signing)

Final Audit Report 2020-09-30

Created:	2020-09-30
By:	Sinead Callinan (sinead.callinan@thinkresearch.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAX2lDlSSEjvjbb3UZ9j1WO6ADaM3a6_3N

"CRF.SPN.000- V1 Glossary of Definitions (signing)" History

Document created by Sinead Callinan (sinead.callinan@thinkresearch.com)
2020-09-30 - 12:52:21 PM GMT- IP address: 37.228.249.160

Document emailed to Sinead Callinan (scallina@tcd.ie) for signature
2020-09-30 - 12:52:45 PM GMT

Email viewed by Sinead Callinan (scallina@tcd.ie)
2020-09-30 - 12:52:52 PM GMT- IP address: 37.228.249.160

Document e-signed by Sinead Callinan (scallina@tcd.ie)
Signature Date: 2020-09-30 - 12:53:07 PM GMT - Time Source: server- IP address: 37.228.249.160

Agreement completed.
2020-09-30 - 12:53:07 PM GMT