**"TRIAL SUBJECT GDPR CONSENT - A DO OR A DON'T?"**

Greater Copenhagen Life Science Yearbook 2020 Article Published on 12 March 2020

**Glossary & References:**

Controller / Controlling: As per Art. 4 (7) of the GDPR, "controller" means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; In relation to this article the controller is the sponsor, having drafted the protocol, determining how to use the data and having set out the data processing rules. In a few EU jurisdictions a few sites have been seen to argue – in an attempt to avoid closing DPA's – that i) the site is controller and the sponsor processor, ii) data is generated as result of the standard treatment offered and not because of the protocol mandate, i.e. the data is there in any case, and iii) "processing" does not cover the mere "transfer" to sponsor. When put to the test most sites now, eventually, agree that i) sponsor does determine the purposes and means of the processing, ii) in reality every protocol requires certain IMP specific data to be recorded and IMP treatment does not, by definition, comprise a standard treatment, and iii) "transfer" is actually covered by the GDPR definition of "processing".

CRO: As per GCP Item No. 5.2, "CRO" means "Contract Research Organization", i.e. a contractor to which the sponsor's trial-related duties and functions may be transferred by contract, provided however that the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. Only specifically identified responsibilities transferred will be vested in the CRO, see GCP Item No. 5.2.3 ("Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor"), whose main task normally will be to implement quality assurance and quality controls.

CTA: A "Clinical Trial Agreement" is an agreement entered into between sponsor and a site (a CTA per site is required) participating in a Clinical Trial, i.e. an investigation in human subjects 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. As per GCP Item No. 1.12, the terms clinical trial and clinical study are synonymous.

CTR: Clinical Trial Regulation (Regulation (EU) No 536/2014) is expected to come into application during 2020. The CTR will be repealing the existing EU Clinical Trial Directive (EC) No. 2001/20/EC and will harmonise the assessment and supervision processes for clinical trials throughout the EU, via a Clinical Trials' Information System (CTIS). CTIS will contain the centralised EU portal and database for clinical trials foreseen by the CTR, which will be set up and maintained by the European Medicines Agency (EMA) in collaboration with the Member States and the European Commission. The authorisation and oversight of clinical trials remains the responsibility of Member States, with EMA managing CTIS and supervising content publication on the public website, see https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf.

CXO: A generic term referring to all corporate executives, whose job title starts with 'Chief' and ends with 'Officer.'

Data Minimisation: As per Article 5(1)(c) of the GDPR personal data shall be: "*adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')*". The data minimisation approach, which as per Article 25 of GDPR shall be applied by default to '*each specific purpose of the processing*', means that sponsor must only collect the minimum amount of personal data that is required to conclude on whether the study has reached the endpoints, whether primary, secondary or surrogate endpoints, defined in the protocol. The data minimisation requirement means that sponsor cannot ask for more data to be collected (or processed) than what is necessary to sustain the purpose of the protocol. The *data minimisation principle* sits alongside the 'purpose limitation' principle set out in Article 5(1)(b) of the GDPR, which states that the purpose for which personal data is collected, must be '*specified, explicit and legitimate*' and the storage limitation principle set out in Article 5(1)(e), which states that personal data should be kept 'no longer than is necessary' for the purposes for which it is processed, see the retention comments under "Pseudonymised data": below.

DPA: Art. 28 (3) of the GDPR requires sponsor to enter into a "Data Processing Agreement" with each and every entity which, e.g., collects, records, organizes, structures, storages, adapts, retrieves, consults, uses, discloses by transmission, disseminates or otherwise makes available, erases or destroys clinical data, all to ensure GDPR compliance and protection of the rights of the trial subject. This means that sponsor must enter

into DPA's with its CRO (and sub-CROs), each site and investigator, laboratories handling biological samples, where the sponsor assumes the controller function for protocol mandated data. The DPA must set out the subject-matter and duration of the processing, i.e. potentially up to 25 years+ as per Art. 58 of the CTR, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller. The DPA must further require e.g. the site / investigator only to processes the trial data on documented sponsor instructions, including with regard to transfers of personal data to a third country (Caveat: UK), and require processor assistance in ensuring compliance with the obligations pursuant to Art. 32 – 35 (processing security, personal data breach notifications and DPIA) of the GDPR.

DPIA: Art. 35(1),(3)&(7) + Recitals 84 & 90 of the GDPR: A data protection impact assessment (DPIA) is required to be made by sponsor, when a type of processing required is likely to result in a high risk to the rights and freedoms of natural persons. Although clinical trial generated data seldom, if ever, produces legal effects concerning or significantly affecting the trial subject as such, and although sponsor will only have access to pseudonymised data (monitor insight disregarded), the data will normally qualify as "special category data" comprising, inter alia, data revealing racial or ethnic origin, genetic data, data concerning health or data concerning a natural person's sex life or sexual orientation, as per Art. 9 (1) of the GDPR. Considering also CTR, Art. 58 calling for data to be archived for 25 years+ going forward, we recommend for each sponsor to prepare a DPIA as a tool to get the required DPAs right, considering that a DPIA must contain a systematic description of the envisaged processing operations, the purposes of the processing, including, where applicable, the legitimate interest pursued by the controller, an assessment of the necessity and proportionality of the processing operations in relation to the purposes, calling for the sponsor to think through which data that is actually required.

DPO / Data Protection Officer. As per GDPR Art. 37 the controller (sponsor) and and the processor (each investigator) shall designate a data protection officer in any case where the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or the core activities of the controller or the processor consist of processing on a large scale of health data. As stipulated in the article, we do not consider biotech companies as the one described as being required to appoint a DPO implying that the Project Manager will be appointed contact person for GDPR purposes, but only as a subordinate function sustaining the key Project Manager tasks required to be solved for the trial to be run.

EC / IRB: An independent ethics committee (IEC), or for the purpose of this article an ethics committee (EC), which in the US is also known as an Institutional Review Board (IRB), is a type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical. Such boards are formally designated to approve (or reject), monitor, and review biomedical and behavioural research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be conducted. The purpose of the EC/IRB is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a clinical trial, reference is made to GCP, Chapter 3, EC /IRB Responsibilities. In the GCP efficacy guideline the terms are used interchangeably, although defined differently in GCP Items Nos. 1.27 and 1.31: As per GCP Item No. 1.27, "Independent Ethics Committee (IEC)", means 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 IEC's may differ among countries, but should allow the IEC to act in agreement with GCP. As per GCP Item No. 1.31 an Institutional Review Board (IRB) comprises 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.

Essential Documents: As per GCP Item No. 1.23 Essential Documents are documents, which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced, See also GCP Chapter 8 (Essential Documents for the Conduct of a Clinical Trial). Essential documents include trial subject data in their pseudonymised format implying that the investigator must agree to maintain the medical records and the codes used for pseudonymisation for at least the same period as sponsor must keep the data on file for regulatory follow-up.

EU Data Protection Board: As per GDPR Art. 68 – 76, the Union has established the European Data Protection Board (the "Board"). As per Art. 70 the tasks of the Board are to ensure, inter alia, consistent application of the

GDPR, including by, inter alia, advising the Commission on any issue related to the protection of personal data in the Union, on the format and procedures for the exchange of information between controllers, processors and supervisory authorities for binding corporate rules, and to issue guidelines and recommendations on a variety of GDPR related aspects.

GCP: ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For, Good Clinical Practice ICH, E6(R2), ICH Consensus Guideline https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

GDPR: Regulation (EU) 2016/679 of The European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), see: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=DA#d1e1797-1-1

GDPR Consent: In principle obtaining consent from a trial subject to process subject data can be sought as per Art. 6(1)(a) and 9(2)(a) of the GDPR. However, consent should under no circumstances be used as legal basis for the processing. In addition to the legal basis comments provided below, the Medical Research Council (MRC), which is part of UK Research and Innovation, see https://mrc.ukri.org/news/blog/gdpr-research-changes/, expressly stipulates that "*Consent is not a requirement of the new data protection laws.*" This should not be confused with the GCP consent, which certainly is required, see ICF below, but 'consent', as defined by GDPR, is not a suitable lawful basis for processing personal data for research purposes whereby the otherwise applicable need for the subject to re-consent on a regular basis is also made redundant. This is important as sponsors in practise would probably never ask for re-consents once the study had been closed out and data archived. In spite of no GDPR consent being required, sponsor must still operate de minimis data processing standards comprising DPA closing, data minimisation, data security and communicate a suitable privacy statement in the ICF.

ICF / Informed Consent Form: As per GCP Item No. 2.9 a freely given informed consent must be obtained from every trial subject prior to clinical trial participation. As per GCP Item No. 1.28 Informed Consent comprises 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 ICF / informed consent form. The ICF comprises the mandatory GCP consent, which should not be mixed up with a GDPR consent, which should be avoided, see GDPR Consent above and Legal Basis below.

ICO: The UK Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, SK9 5AF, England, Website: www.ico.org.uk, Tllph. +44 0303 123 1113, e-mail: mail@ico.org.uk, which authority enforces personal Data Processing legislation applicable in the UK, but which also – before UK became a third country following Brexit – has published valuable guidance notes and templates on GDPR application.

IMP / Investigational Medicinal Product: As per Art. 2.2 (5) of the CTR, an "investigational medicinal product" is a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial. As per GCP Item No. 1.33 an "Investigational Product" is 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.

Legal basis: Processing of personal data requires that the controller has a valid lawful basis, which may comprise the following 6 alternatives: (a) Consent; (b) Contract; (c) Legal obligation; (d) Vital interests; (e) Public task; or (f) Legitimate interests. Although none of these theoretically are 'better' or more important than the others, we may first of all note that for clinical trial purposes only (a) Consent and (f) legitimate interests, are to be considered. As per the GDPR Consent note above, we strongly advise against using the (a) Consent route, and urge sponsors to use only (f) legitimate interests. Further it is necessary to note that as protocol derived pre-submission trial health data as per GDPR Art. 9(1) comprises "special category data", which as per a starting point must not be processed at all, the lawful basis used for processing purposes as per the above, must be supplemented by a reference to Art. 9(2)(j) – but not 9(2)(a), consent - comprising the relevant main rule exception in case of research. see https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/.

Medical confidentiality: Although trial subject health data are being collected as per a protocol, i.e. with the sponsor as controller, the data will be collected by or under the authority of investigator being a medical doctor. As processor the investigator is only authorised to report protocol mandated data to sponsor, which is done by completion of CFRs. Other data, including the identity of the subject, is subject to the principles of medical confidentiality, which must be complied with, i.e. that sponsor has no rights (but limited monitor review rights) to personal data, which are not to be included in the CRF's as per the Protocol. Were sponsor subsequently to require access to trial subject identification codes, e.g. because of adverse reactions, which need to be followed-up upon, such access can only be obtained via investigator, who may only disseminate such data to sponsor if a proper legal basis for such dissemination may then be identified, e.g vital interests.

MSA / Master Service Agreement: An agreement between sponsor and a chosen CRO, describing the trial related services to be rendered by the CRO. In principle of a variety of service providers use a MSA format, when an umbrella wording generally applicable to the rendering of various services is required.

Processor / Processing: As per Art. 4 (2) of the GDPR, "processing" means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. Any investigator handling of data as per a typical protocol will involve processing calling for a DPA to be entered into between sponsor as controller and investigator as processor.

Pseudonymised data: As per Art. 4 (5) of the GDPR, "pseudonymisation" means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. Even though trial data is pseudonymised, investigator must keep in his records an identification code enabling re-identification of the subject for as long as the data is on file (25+ years as per the CTR). Pseudonymised data remain being subject to GDPR as re-identification is possible even though only investigator can do the re-identification.

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