

POLSOP003: Cmed Policy on Safe Harbor

1.0 Policy

It is the policy of Cmed Group (Cmed) to abide by the European Legislation for the Protection of Data. It is Cmed's policy that the principles (if not requirements) of the European Directive on Data Protection and the Data Protection Act in the United Kingdom (UK) will be followed by the Cmed Group Ltd globally, meaning by all its subsidiary companies, including Cmed Inc. Cmed Inc. is a wholly owned US-registered subsidiary of Cmed Group Ltd.

To provide further assurance of this commitment, Cmed Inc. has developed this policy to comply with the requirements set forth by the US Department of Commerce for the US-EU Safe Harbor Framework.

Cmed Inc. is involved in clinical trials that are, by nature, global in scope. As such Cmed Inc., may, from time-to-time, receive confidential information that has been collected from within the European Union and therefore subject to the European Directive on Data Protection. As such it is important that Cmed self certify as a Safe Harbor for such data to ensure that it complies with the European Union's data protection directive. This affords the same level of protection to the data as would be provided had the data stayed within the confines of the European Union.

Cmed Inc. hereby states that it will adhere to and comply with the Safe Harbor requirements as laid out by the Department of Commerce and the US Federal Trade Commission.

Cmed Inc. will retain, in the strictest confidence, the data collected from clinical trials wherever that material is collected or transmitted from. Although individuals may consent to their data being used and transmitted, Cmed Inc. will ensure that this information is protected in such a way that it respects the trust of the consenting individuals.

2.0 Principles

2.1 Notice

In terms of its clinical trial work Cmed is not directly responsible for informing individuals of the purpose for which their data is being collected. This responsibility is undertaken by medically qualified investigators working directly for a client or sponsor company on a clinical trial. Cmed Inc. may, however, have responsibility for checking the validity, appropriateness and obligations of the medically qualified clinical trial investigators (or designees) who assume the responsibility for informing individuals about the purpose for which their data is being collected.

Each individual participating in the clinical trial will be informed about the clinical trial via a verbal discussion and an Informed Consent Form. The Informed Consent Form details the principles of the trial and the nature of the collection, documentation and reporting of that data. Individuals consent to the use of their data by signing the Informed Consent Form for the trial. Cmed Inc.

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will not use or disclose the data beyond that stated in the Informed Consent Form. If changes become necessary, individuals will be asked to re-consent to those changes before the amendment is put into practice.

Cmed does not collect participant information such as name and address throughout the conduct of any clinical trial. All data is effectively anonymised. Participant data is usually identified for consistency reasons by means of a dedicated subject identifier which the sponsor applies to each participant enrolled in the trial. Cmed has no knowledge that would allow it to identify individuals from a sponsor supplied subject identifier. Occasionally the Sponsor will include participant initials as an additional check so that when the data for a particular participant is assembled, checks may be applied to ensure that all data belongs to that particular individual. It is however, practically impossible for Cmed to associate the data collected with the individual who provided that data in the first place.

Notwithstanding the above, where Cmed Inc. directly collects personal data from individuals residing within the EU (i.e. not on behalf of a client or sponsor company, and where consent for use of the data outside of the EU has not been obtained) then it will also notify them about the purposes for which that information has been collected.

2.2 Choice

At any point during a clinical trial, the participant has the opportunity to withdraw from the trial and has the option to prevent their personal data from being used in the clinical trial from that point onwards. The participant has the opportunity to see what information has been collected about them to confirm that it is the same as they consented to; however this information may not be able to be divulged immediately dependent upon the status of the trial in which they have participated.

2.3 Onward Transfer

Cmed Inc. will not disclose any personal information to anyone beyond that stated in and consented to by the individual listed on the Informed Consent Form. The onward transmission of the data will typically go no further than other Cmed offices. In the case where Cmed is acting as a third party to the sponsor, the sponsor is the “owner” of any data transferred to them by Cmed. On rare occasions, an individual's data may be reviewed by one of the third party government monitoring authorities but the data will only be used to confirm that the clinical trial has met the requirements of the legislation and no further. The individual will have consented to this requirement by signing the Informed Consent Form.

2.4 Security

Cmed Inc. shall ensure that the data collected will remain in a secure environment free from unauthorized access. Cmed Inc. has put in place appropriate physical, electronic and

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managerial procedures to safeguard and secure the data from loss, misuse, or external access. Should a data breach be discovered, Cmed Inc. will use its Standard Operating Procedures to record and correct the breach.

2.5 Data Integrity

Cmed Inc. shall only process personal information in a way that is compatible with and relevant to the purpose for which it was collected or consented to by the individual. To the extent necessary for those purposes and in line with Good Clinical Practice legislation, Cmed Inc. will take all reasonable steps to ensure that personal data is accurate, complete, current and reliable for its intended use.

2.6 Access

Cmed Inc. shall grant an individual access to their personal information and allow the individual to correct, amend or delete inaccurate information, except where the burden or expense of providing access would be disproportionate to the risks to the privacy of the individual in the case in question or where the rights of persons other than the individual would be violated. However, since Cmed Inc. collects this data on behalf of the developer of the investigational product, permission will be sought from the data owner for the timing of access to the data by the individual.

2.7 Enforcement

Cmed Inc. uses a self-assessment approach to assure compliance with this privacy policy and periodically verifies that the policy is accurate, comprehensive for the information intended to be covered, completely implemented, accessible and in conformity with the Principles. Cmed Inc. encourages interested persons to raise any concerns using the contact information provided which will be investigated by Cmed Inc's independent quality assurance department. An attempt to resolve any complaints and disputes regarding use and disclosure of personal information will be made in accordance with the Principles. If a complaint or dispute cannot be resolved through our internal process, we agree to dispute resolution using an independent resource mechanism as a third party resolution provider. This provider will be the EU Data Protection Authority.

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If an individual feels they wish to query or dispute the information stored by Cmed Inc. or they have an issue with the processes concerning this policy, the following people can be contacted to initiate the review process.

Name	Title	Contact Information
Mark Holt	Chief Operating Officer (US)	Cmed Inc., 430 Mountain Avenue, 4th Floor, Murray Hill, NJ 07974, United States. mholt@cmedresearch.com
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