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BRE-JBZ

From: Kaai, Geran
Sent: vrijdag 3 april 2015 16:00
To: Verweij, Ellen
Subject: FW: Proposed EU Data Protection Regulations - COM(2012) final
Attachments: 2012 02 25 Quintiles - Analysis of Issues Re the Draft Albrecht Report on the EU DP Reg- Feb 2013 CL.DOCX; Quintiles - Detailed Analysis of Issues Re the Proposed EU DP Regs- Oct2012.docx; Quintiles - Amendments on the Proposal for a Regulation- Oct2012.docx; ATT00001.txt

Follow Up Flag: Follow up
Flag Status: Completed

From: [mailto:
Sent: woensdag 27 februari 2013 11:44
To: Kaai, Geran
Subject: FW: Proposed EU Data Protection Regulations - COM(2012) final

Dear Mr. Kaai,

Further to our email last October, we provide our additional comments and concerns to the recent report and amendments from on the proposed Regulations.

We would request your further review and consideration of our concerns with regards proposed amendments.

We thank you for the opportunity to engage with you on this important matter, and remain at your disposal if you have any further questions.

Kind regards,

EU Data Protection

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clinical | commercial | consulting | capital

From: [redacted]
Sent: 22 October 2012 17:38
To: 'geran.kaai@minbuza.nl'
Subject: Proposed EU Data Protection Regulations - COM(2012) final

Dear Mr. Kaai,

We are a leading contract research organisation (CRO) operating within the Life Sciences industry, and consequently, handle enormous volumes of personal data for medical research, treatments, therapies and drug development. We very much appreciate the encouragement from the European Commission, the Representatives from the Permanent Representations and the Members of the European Parliament to contribute to the development of this proposed Regulation.

During our review of the proposed text we have identified areas of concern where the current iteration of the proposed Regulations could give rise to unintended consequences for the Life Sciences Industry, potentially to the ultimate detriment of medical research advancement and public health.

In the attached documents which we provide for your review and consideration, we have provided a Summary of those Issues of primary concern to Quintiles, and table our suggested Amendments to the proposed draft Regulation to address these concerns.

Also attached is a copy of a generic template version of an Informed Consent Form (ICF). We thought it would be useful to attach this as a reference document to our comments on Consent and Lawfulness of Processing, since the patient informed consent process is fundamental to the conduct of a clinical trial. The contents of these ICFs are generally prescribed by the Good Clinical Practice Guidelines. Whilst this ICF is generic, country specific ICFs (which meet local regulatory requirements) are generated from the generic templates. We have different template ICFs for Paediatric and for specific types of clinical trial studies, and would be happy to forward other sample templates to you, if you are interested.

We have had the opportunity to meet and discuss our concerns with certain of your colleagues but unfortunately not with yourself. Nevertheless, we remain at your disposal for any questions you may have, and look forward to having an opportunity to engage in discussions with you in the future on this important matter.

Yours sincerely,

[redacted]

[redacted] EU Data Protection

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