FUEHRING Stefan (ENTR)

From: ENTR /F/2 PHARMACEUTICALS
Sent: lundi 7 septembre 2009 11:09
To: FUEHRING Stefan (ENTR)
Cc: SALVADOR ROLDAN Rocio (ENTR); ATZOR Sabine (ENTR)
Subject: FW: Comments from GE Healthcare Ltd. Re Authorisation of a clinical trial to the competent authorities, substantial amendments.....

A/21253

From: Matthews, Yvonne (GE Healthcare) [mailto:Yvonne.Matthews@ge.com]
Sent: Monday, September 07, 2009 11:03 AM
To: ENTR /F/2 PHARMACEUTICALS
Subject: Comments from GE Healthcare Ltd. Re Authorisation of a clinical trial to the competent authorities, substantial amendments.....

Please find the comments below to the guideline " Authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial" replacing the guideline of 2005.

GE Healthcare Ltd. supports the revision to this guideline:

The proposed revision is much easier to understand, it includes a good range of examples of substantial and non-substantial amendments, clarifies format of covering letters for the CT application and content of notifications, clarifies situations around temporary halt of a trial and urgent safety measures. It includes guidance relating to Paediatric Investigational Plans and first time in man studies. It makes it clear that the definition of the of the end of the trial must be included in the protocol.

Kind regards

Yvonne

Yvonne Matthews
Regulatory Operations Executive
GE Healthcare

T +44 1494 543295
F +44 1494 545137
D *378-3295
E yvonne.matthews@ge.com
www.gehealthcare.com

The Grove Centre
White Lion Road
Bucks
Amersham
HP7 9LL
UK
General Electric Company
GE Healthcare Limited

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