To whom it may concern
Please see communication below for a suggestion for an electronic EU CTA through a common Portal using the eCTD modules.
We may then use the tools we have for preparation of eCTDs also for EU CTAs. This will allow us/SMEs to use global modules right from the beginning of the development of a medicinal product and using only one format independently of submission. The eCTD facilitates the use of modules in any submission. This may also enable the agencies to use their current review tools.

Please do not hesitate to return in case I can be of any assistance in discussing this matter.

Med venlig hilsen/Best Regards

Inge Andersen

-----Original Message-----
From: Sweeney Fergus [mailto:Fergus.Sweeney@ema.europa.eu]
Sent: 4. maj 2011 20:48
To: Inge Andersen
Cc: Wagner Hans-Georg; EMA Info
Subject: RE: CTAs in the EU for SMEs RFI-2011 No 05-024

Dear Inge,
I would suggest that you could communicate your suggestions directly to DG SANCO pharmaceuticals unit in the context of their review of the clinical trial legislation - for which they are collecting input up to 13 May 2011.

http://ec.europa.eu/health/files/clinicaltrials/concept_paper_02-2011.pdf

Comments to sanco-pharmaceuticals@ec.europa.eu by 13 May 2011.

You could comment on the point below on its own, in the context of a single EU Portal, or add other suggestions relating to the other aspects set out by the Commission, Best Regards Fergus

Fergus Sweeney Ph.D. | Head of Sector, Compliance and Inspection European Medicines Agency | 7 Westferry Circus | Canary Wharf | London E14 4HB | United Kingdom Tel. +44 (0)20 7523 7026 | Fax +44 (0)20 7418 8595 | fergus.sweeney@ema.europa.eu | www.ema.europa.eu As of 8 December 2009, the URL of the Agency's website and e-mail addresses has changed from 'emea.europa.eu' to 'ema.europa.eu'. Please update your bookmarks and address books accordingly.

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From: Inge Andersen [mailto:iwa@iwaconsulting.dk]
Sent: 04 May 2011 08:40
To: WF EMEA Requests
Subject: FW: CTAs in the EU for SMEs RFI-2011 No 05-024

To whom it may concern
Please forward to Hans Georg Wagner as per his request at a recent meeting in Mallorca.
Thanks for your help.
Med venlig hilsen/Best Regards
Inge Andersen
From: Inge Andersen
Sent: 3. maj 2011 11:17
To: 'hans.georg.wagner@ema.eu.int'
Cc: Lillan Rejkjaer
Subject: CTAs in the EU for SMEs
Dear Hans Georg Wagner
It was interesting meeting and talking to you at the eRA meeting in Mallorca April 2011.
As discussed please find some comments on CTAs for the EU which would help SMEs.
We are currently working with small companies very often SMEs within the area of Biotech and are aiming at having one global core dossier for the complete development.
The structure of the eIND is just an eCTD for modules 2-5 including what is available at the time of submission to support the proposed clinical trial.
All other documents required for the IND are placed in M1.
Global dossiers for these companies are thus the eIND/eCTD to ensure the documents are version controlled during the complete development and eventually the NDA is all sequences or the consolidated dossier.
We would be very happy on behalf of these small companies if the EU would take the same approach for CTAs resulting in an IMPD corresponding to the eCTD as well.
If summaries will be required instead of the actual study reports the IMPD may consist of the following sections as appropriate:
M2.3
M2.4- 2.6
M2.5-2.7.6
Protocol in M5
Forms and risk/benefit statement for this particular study may go to M1; as well as IB (1.3.1)
M1 may follow the same specifications as we have today for a an application; i.e. all additional data and manufacturing licenses should be annexes to the application form.
This would facilitate the transformation of the CTAs to electronic format as well as making life easier for small companies.
Med venlig hilsen/Best Regards
Inge Walløe Andersen
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