

Email to FDA MDDT review team 20170419

From: Gallas, Brandon D.
Sent: Wednesday, April 19, 2017 9:51 AM
To: MDDT
Cc: Lochner, Donna R.; Scharen-Guivel, Hilda; Krainak, Daniel
Subject: RE: MDDT031 Proposal Acknowledgement Letter

Good morning everyone.

The WSI working group members on this eeDAP-MDDT project have had T-cons to plan the studies to support the eeDAP MDDT. We are all anxious to hear back so that we proceed in the right direction. We are falling behind in our plans for developing our protocols and logistics and are feeling pressure because we have committed to providing an update to the larger WSI working group and the public at the Pathology Informatics Summit May 21-25.

Can you please let us know what is going on?
When can we expect a response?

We also have a big question that we would like feedback on. Specifically, we have outlined plans to conduct reader studies to provide evidence to support the context of use (pathologist performance). We have also outlined plans to characterize the accuracy of the image registration process and the color reproduction (technical performance).

Can this MDDT be approved with only technical performance data?

Can this MDDT be approved with only technical performance data if we were to change the context of use?

If a new context of use is necessary, can you help us reframe the context of use so that this MDDT can be approved with only technical performance data?

Thanks,

Brandon Gallas and the WSI Working Group eeDAP-MDDT project members

From: Gallas, Brandon D. Sent: Wednesday, March 08, 2017 2:51 PM To: MDDT Cc: Lochner, Donna R.; Scharen-Guivel, Hilda; Krainak, Daniel Subject: RE: MDDT031 Proposal Acknowledgement Letter

Thanks for the update. I was wondering ...

Brandon

From: MDDT Sent: Wednesday, March 08, 2017 1:52 PM To: MDDT; Gallas, Brandon D. Cc: Lochner, Donna R.; Scharen-Guivel, Hilda; Krainak, Daniel Subject: RE: MDDT031 Proposal Acknowledgement Letter

Good Afternoon Dr. Gallas,

MDDT031 is still under consideration. We will contact you on how to proceed once a decision has been made.

If you have any questions, please feel free to contact me.

v/r

Joan Adams-White Regulatory Health Project Manager Food and Drug Administration
CDRH/OCD/CSC 10903 New Hampshire Ave WO66, Room 5519 Silver Spring, MD 20993 Off:
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From: MDDT Sent: Friday, January 27, 2017 3:49 PM To: Gallas, Brandon D. Cc: MDDT;
Lochner, Donna R. Subject: MDDT031 Proposal Acknowledgement Letter

Good Morning Dr. Gallas,

Thank you for your interest in the MDDT Pilot Program. Please see the attached MDDT031 Proposal Acknowledgment of Receipt. We will review your proposal and communicate our determination regarding acceptance into the MDDT Pilot Program within 30 days of receipt.

Regards,

The MDDT Program Staff MDDT@fda.hhs.gov