

From: Brennan, Michael [JRDUS] [MBrenna3@its.jnj.com]
Sent: Friday, October 07, 2011 9:15 AM
To: Garvey, Patricia
Cc: Edward Tripp
Subject: RE: DRAFT Project Scope Statement: CDA IG for Exchange of Clinical Trial Subject Data: Patient Narrative

Patty:

I have reviewed and accept the Project Scope Statement. Please include J&J to the implementers.

If I have a concern is that the free text part of the narrative may repeat information provide as structured data (i.e., folks write narratives as they have in the past). This could present a problem for potentially reconciling structured information and information contained within the free text narrative.

This is **not** an issue for the PSS. I believe that this can potentially be addressed during testing and might be included in an implementation guide.

Nice work – eager to see this move forward.

Ed – I have a conflict on 11 Oct (PhRMA ERS Meeting). If you need a quorum, I could call into the beginning of the RCRIM Meeting. Hopefully this email will suffice to register my approval.

Michael

From: Garvey, Patricia [<mailto:Patricia.Garvey@fda.hhs.gov>]
Sent: Friday, October 07, 2011 9:27 AM
To: Brennan, Michael [JRDUS]
Subject: RE: DRAFT Project Scope Statement: CDA IG for Exchange of Clinical Trial Subject Data: Patient Narrative

Unfortunately, this is a regularly scheduled meeting so I won't be able to reschedule the meeting. Also, the deadline to submit this PSS was last week so RCRIM need to get an approval vote and move it forward for TSC approval ASAP.

You can send your comments to me but I would request that if you approve of the PSS to let Ed Tripp know.

Patty Garvey, R.Ph.

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From: Brennan, Michael [JRDUS] [<mailto:MBrenna3@its.jnj.com>]
Sent: Friday, October 07, 2011 9:15 AM
To: Garvey, Patricia
Subject: RE: DRAFT Project Scope Statement: CDA IG for Exchange of Clinical Trial Subject Data: Patient Narrative

Patty:

I have a conflict on 11 Oct (and guess the same for Bill Friggle) – PhRMA meeting.
I will review and get comments to you before the meeting.
Any chance that we might reschedule?
Michael

From: Garvey, Patricia [<mailto:Patricia.Garvey@fda.hhs.gov>]
Sent: Friday, October 07, 2011 9:01 AM
To: Brennan, Michael [JRDUS]
Subject: RE: DRAFT Project Scope Statement: CDA IG for Exchange of Clinical Trial Subject Data: Patient Narrative

Michael,

The document will be review during the RCRIM on Tuesday, October 11th. I will share your information during the meeting.

Thanks for you support.
Patty

Patty Garvey, R.Ph.

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From: Brennan, Michael [JRDUS] [<mailto:MBrenna3@its.jnj.com>]
Sent: Thursday, October 06, 2011 2:30 PM
To: Garvey, Patricia
Subject: RE: DRAFT Project Scope Statement: CDA IG for Exchange of Clinical Trial Subject Data: Patient Narrative

Patty

I sent out a note this morning and got confirmation of interest on J&J part.

Michael

From: owner-rcrimdisc@lists.hl7.org [<mailto:owner-rcrimdisc@lists.hl7.org>] **On Behalf Of** Garvey, Patricia
Sent: Thursday, October 06, 2011 2:25 PM
To: rcrimdisc@lists.hl7.org
Subject: DRAFT Project Scope Statement: CDA IG for Exchange of Clinical Trial Subject Data: Patient Narrative
Importance: High

Hello Stage 2 members,

Please review the attached DRAFT Project Scope Statement for CDA Implementation Guide for the Exchange of Clinical Trial Subject Data: Patient Narratives. I have missed the deadline for submitting the project scope statement for balloting in January 2012. Ed Tripp is trying to work with HQ to get approval to get this submitted late.

In the mean time, I'm going to proceed with moving this forward for review and approval during this coming Tuesday, October 11th

RCRIM meeting in the event the a late submission is allowed. Therefore, please review and provide me with any feedback as soon as possible.

Please let me know if you have any questions.

Thanks,
Patty

Patty Garvey, R.Ph.

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