CIOMS WG on Vaccine Safety

1) Deliverable 1: CIOMS Guide for Active Vaccine Safety Surveillance
   a) Status: Guide for AVSS, approximately 85 pages.
      File: G:\UnitData\aCIOMS Working Groups\WG on Vaccine Safety\CURRENT VERSION\CURRENT FINAL EDBD COMMENTS July 2016\ Cioms guide AVSS_master_29_ July.docx
      i) Content approved by WHO and Editorial Board, includes deliverables from topic group 1 (essential vaccine information) and topic group 2 (the guide).
      ii) Contact: Steven Bailey, Ed-in-Chief of report of the CIOMS WG on Vaccine Safety , Steven R. Bailey, MD MPH MBA
      Vice President, Worldwide Safety and Regulatory
      Global Established Pharma Safety Lead, Pfizer
      Tel. +1 484 865 3670 Steven.R.Bailey@pfizer.com

   b) Pending issues:
      i) Should be reviewed by Secretary-General, especially Appendix 1 on Essential Vaccine Information which describes delicate national regulatory issues and Appendix 2 on membership list, where I have highlighted stakeholder category and member inclusion issues needing S-G advice.
      ii) Steven will circulate one last time to EdBd for comments and final edits, if any, for returning to CIOMS by 5 August.
      iii) WHO-style editing to prepare for printing: David Bramley is not available, I have forwarded the c.v. and contacts of 6 alternatives to Sue le Roux.
      iv) In Appendix II. Membership and Meetings of the CIOMS Working Group on Vaccine Safety, I still have some highlighted questions on how to describe certain organizations/stakeholders, since there could be some sensitivity.
      v) In Appendix II, I still have some questions on any inactive WG members to include for political reasons. None of these individuals attended any meetings nor provided feedback to me, but they may have been active behind the scenes or provided support within their organizations (albeit invisible to us). Two possible names to consider from Steven Bailey's point of view: William Gregory and Peter Arlett. Also Bernhard Heiles of Merck definitely did preparatory work, but then never attended a meeting and sent Ashley Wivel as a replacement.
      vi) Executive Summary and Article Publications –
      File: G:\UnitData\aCIOMS Working Groups\WG on Vaccine Safety\CURRENT VERSION\EXECUTIVE SUMMARY ARTICLES\EXECUTIVE SUMMARY_v1_UH pz.docx
      Uli Heininger wrote this based on some drafts of chapter summaries by Frank Destefano and Scott Winiecki and Irina Caplanusi (who should also get some authorship). Steven is circulating for comments to rest of EdBd, Zuber has already added comments. It needs to be updated concerning the EVI section which I have written in Appendix 1. Uli has offered to submit to Vaccine Journal, and Brighton Collaboration Quarterly. I suggest also PLOS One, at least along with all the normal ones (BMJ, Lancet, Nature, NEMJ?).
      vii) Printers: Suggested cover color: A turquoise blue to be in the same group as Vaccine PV Definitions (which is a sky blue) Pantone 318U, Pts 1, BL 6.3, Pts 1 GR 6.3, Pts 14 87.4.

   c) Publicity and Role-out

i) Blurb needs to be written (could be based on Executive summary (see above I.b.iv) and sent to WHO bulletin, BMJ, Lancet, Nature, NEMJ, Vaccine, Brighton Collaboration, etc.
ii) Powerpoint presentations needs to be developed – especially for Ed Bd to use at upcoming conferences.
iii) Poster created possibly.
iv) Christine Maure, WHO, wants to use the manual in China next month and so could possibly be interested in contributing to this effort.

2) Deliverable 2: CIOMS Comprehensive Communication Guide for Vaccine Safety
   a) Status: Written document needs finalization by key author Bahri and topic group 3 members and then CIOMS editing review and WHO input.
   b) File: G:\UnitData\aCIOMS Working Groups\WG on Vaccine Safety\CURRENT VERSION\TG3 Vaccine Safety Communication\10 TG3 Draft chapter_11 March 2016.docx
   c) Contact: Dr. Priya Bahri, topic group 3 leader, EMA
   Lead for EMA's pharmacovigilance guideline development (EU GVP) and risk communication.
   +44 (20) 3660 8454 priya.bahri@ema.europa.eu
   d) Pending issues:
      i) CIOMS and Zuber agreed in principle to publish the document separately to be a companion document to the Guide for AVSS, under CIOMS publishing. Support from WHO to be negotiated.
      ii) Priya has been referring to this potential doc in some EMA work she has been doing, so the CIOMS guide could be cross-referenced throughout European initiatives.
      iii) Bruce Hugman from UMC contributed and Ken Hartigan-Go is very interested in it as well.

3) Requested Deliverable: private sector – regulatory information exchange and dialogue
   a) File: G:\UnitData\aCIOMS Working Groups\WG on Vaccine Safety\CURRENT VERSION\PUBLIC-PRIVATE INTERACTION \ symposium proposal on private-public interaction srb_9june.docx
   b) Zuber is exploring with Mike Ward of DCVRN who though could be a good topic for discussion at the spring 2017 meeting. There is no venue yet identified but it is usually in one of the member states (Brazil, Cuba, India, Indonesia, Islamic Republic of Iran, People's Republic of China, Republic of Korea, South Africa and Thailand).

Karin R. Holm
Technical Collaboration Coordinator, CIOMS WG on Vaccine Safety
CIOMS IX Risk Minimisation and CIOMS X Meta-Analysis
Council for International Organizations of Medical Sciences (CIOMS)
c/o WCC, P.O. Box 2100, CH-1211 Geneva 2, Switzerland
Phone: +41 22 791 6497 Website: www.cioms.ch
Email: holmk@cioms.ch
Associate partner of UNESCO
In official relations with WHO

From: Bailey, Steven R.
Sent: Sat, 30 Jul 2016 14:27:11 +0000
To: Zuber, Patrick (CDC who.int);Corinne.Jouquelet-Royer@sanofipasteur.com;Paulo.santos@bio.fiocruz.br;novilia@biofarma.co.id;Destefano, Frank (CDC/OID/NCEZID);Caplanusi, Irina (alt) (Irina.Caplanusi@ema.europa.eu);'Holm Karin'
Subject: RE: ideas for exec summary

Thanks Patrick.

For the remainder of the Editorial Board, please consider this a friendly reminder to provide any further comments/rewrite please. We are hoping to finalize this and have it back to CIOMS by this upcoming Friday.

A few additional notes to the Editorial Board:

1) Sadly, this past Friday was Karin's last day at CIOMS. Her energy and leadership will be missed by all of us. Before "signing off" she did a very good job wrapping up most of the issues with our document. It is, for all intents and purposes of this group complete. It needs a few minor tweaks regarding acknowledgements/etc. that CIOMS will be working on, and is being prepped for printing. I will share the final version soon when it is cleaned up.
2) There will be some additional activities (such this executive summary and some materials for presentation/publicity) that are still to come, so your continued support will be appreciated.

Regards

Steven.

Steven R. Bailey, MD MPH MBA
Vice President, Worldwide Safety and Regulatory
SSRM RU/Vaccines Group Head
Pfizer
Steven.R.Bailey@Pfizer.com
484 865 3670

From: ZUBER, Patrick Louis F. [mailto:zuberp@who.int]
Sent: Tuesday, July 26, 2016 6:00 AM
To: Bailey, Steven R.; Corinne.Jouquelet-Royer@sanofipasteur.com; Paulo.santos@bio.fiocruz.br; novilia@biofarma.co.id; fxd1@cdc.gov; Caplanusi, Irina (alt) (Irina.Caplanusi@ema.europa.eu); 'Holm Karin'
Subject: RE: ideas for exec summary

Dear Steven,

Thanks to Uli for providing this summary. Please find my comments and proposed edits. I would suggest a slight modification to reflect that active surveillance is not necessarily a population-based activity. This is well explained in the summary table but there was some ambiguity in the first part of the summary that I have tried to address. We had discussed that in the last call and Frank also provided some language.

With best wishes,

Patrick

From: Bailey, Steven R. [mailto:Steven.R.Bailey@pfizer.com]
Sent: Monday, July 25, 2016 8:45 PM
To: Corinne.Jouquelet-Royer@sanofipasteur.com; ZUBER, Patrick Louis F.; Paulo.santos@bio.fiocruz.br; novilia@biofarma.co.id; fxd1@cdc.gov; Caplanusi, Irina (alt) (Irina.Caplanusi@ema.europa.eu); 'Holm Karin'
Cc: Bailey, Steven R.
Subject: FW: ideas for exec summary

Dear Editorial Board:

Please find attached a DRAFT Executive Summary that was put together by Uli Heininger based on part of our Guide that had been part of our document. This executive summary will be important because it will serve as the basis of communications about our work: summaries for stakeholder to make them aware of the Guide, etc.

It would be helpful to get your feedback on this Exec Summary. I will collate suggested edits and comments, and provide back to Uli and others going forward.

Please do note that we are still working on the EVI part of the guide, so that part of this summary will likely need to be updated. And I will share with you those changes as soon as they are settled for Ed Board approval.

Kind regards,

Steven.

Steven R. Bailey, MD MPH MBA
Vice President, Worldwide Safety and Regulatory
SSRM RU/Vaccines Group Head
Pfizer
Steven.R.Bailey@Pfizer.com
484 865 3670

From: Bailey, Steven R.
Sent: Wed, 22 Jun 2016 13:24:38 +0000
To: Destefano, Frank (CDC/OID/NCEZID);Caplanusi, Irina (alt) (Irina.Caplanusi@ema.europa.eu);Corinne.Jouquelet-Royer@sanofipasteur.com;Bachtiar, Novilia (novilia@biofarma.co.id);Paulo.santos@bio.fiocruz.br;Zuber, Patrick (CDC who.int)
Cc: Holm Karin;Bailey, Steven R.;Rago Lembit (ragol@cioms.ch)
Subject: Advanced Draft of the Guide and Next Steps
Attachments: Cioms guide AVSS_master_21june.docx

Dear Editorial Board:

I am very happy to send you this latest, and near final, version of our document. At this point, the document is in very good shape. The vast majority of comments, both internal and external, have been addressed. What remains at this point are key questions that require Ed Board input, and review of some new text added recently (but carefully reviewed by a subset of Ed Board members).

Some very important thanks are due for getting this version together ahead of time. Karin has worked tirelessly to bring all the various piece of text together cogently, as well as providing text of her own and important comments. As well, Frank and Irina have worked very hard to bring their chapters (3 and 4) to this point, addressing a large number of comments. And a special acknowledgement to Scott Winiecki who provided a lot of new text and support.

At present, we were planning on meeting as an Editorial Board until July 12th, which is 3 weeks away. However, given we have a good draft together ready for Ed Board discussion, and that we have a pretty good window of availability for almost everyone on **June 28th,** I am going to schedule an Ed Board meeting for next week on the 28th, 8-11 US time (to follow). This will allow us to get ahead of our timelines.

This is still 6 days away, which will allow you to digest the current draft. I would ask the Ed Board to focus on the following within the document in preparation for next week's meeting:

1) Please review the comments. All remaining questions for the Ed Board are contained in this document in comments.
2) Please review the text highlighted in green. This is text that will be new to some of you, and feedback would be helpful.
3) Now that it is all tied together, your sense of how the overall flow is working: we have made a lot of effort to improve this over the past month, and it would be good to see if the effort has been successful.

At this point, it is critical that we maintain version control. Going forward the MASTER document will be held by Karin, and only she will be making further updates after agreement by the EB. So if you choose to make an edits or comments into this document, be prepared to bring them up at the meeting next week, as they will have to be agreed to by the Ed Board before being placed in the master. Next week we will discuss how we make further revisions (if needed). So if you do start to make edits, please use track changes and clearly mark you edits with comments; we may be able to merge them all together eventually if needed.

As always, I appreciate the efforts everyone has been making to help us complete this project. We are very close to the finish line, and I think we have a very strong document. Your continued engagement over the next 3-4 weeks will help us cross the threshold together and on time.

Regards,

Steven.

Steven R. Bailey, MD MPH MBA
Vice President, Worldwide Safety and Regulatory
SSRM RU/Vaccines Group Head
Pfizer
Steven.R.Bailey@Pfizer.com
484 865 3670

From: Bailey, Steven R.
Sent: Fri, 17 Jun 2016 13:00:13 +0000
To: Zuber, Patrick (CDC who.int);Corinne.Jouquelet-Royer@sanofipasteur.com;novilia@biofarma.co.id;Paulo.santos@bio.fiocruz.br
Cc: Irina.Caplanusi@ema.europa.eu;Destefano, Frank (CDC/OID/NCEZID);Holm Karin (holmk@cioms.ch);Winiecki, Scott (FDA/CBER);Rago Lembit (ragol@cioms.ch);Abdoellah, Siti (alt) (b)(6);Bachtiar, Novilia (novilia@biofarma.co.id);Bahri, Priya (Priya.Bahri@ema.europa.eu);Bailey, Steven R.;Bergman, Ulf (b)(6);Bruce Hugman;BUTLER, Robb;Chandler, Rebecca (alt) (rebecca.chandler@who-umc.org);Gunale, Bhagwat (alt) (bhagwat.gunale@seruminstitute.com);Jouquelet-Royer, Corinne (Corinne.Jouquelet-Royer@sanofipasteur.com);Keller-Stanislawski (Brigitte.Keller-Stanislawski@pei.de);Kilpi, Terhi (terhi.kilpi@thl.fi);Lindquist, Marie (Marie.Lindquist@who-umc.org);Maure, Christine (maurec@who.int);Menezes, Reinaldo de (Rmenezes@bio.fiocruz.br);Mentzer, Dirk (Dirk.Mentzer@pei.de);Nohynek Anna (Hanna.Nohynek@thl.fi);Oberle, Doris (alt2) (Doris.Oberle@pei.de);Santos, Paulo (alt) (Paulo.santos@bio.fiocruz.br);Seifert, Harry (Harry.A.Seifert@gsk.com);Shimabukuro, Tom (CDC/OID/NCEZID);Tebaa, Amina (b)(6);Zuber, Patrick (CDC who.int);DENNISILLA BAIDOO (b)(6)
Subject: Update on Status of Our Guide

Dear Working Group:

I wanted to send you an update on where we stand as an Editorial Board, and the finalization of our guide.

Last week we received some good news that our target date for completion has been moved out to the end of July, which has given the Editorial Board some extra time to review the comments received from many of you, and the 5 external experts we engaged.

All comments have now been received, and are being reviewed by members of the Editorial Board, especially those who have been key chapter authors. They are working to address all these comments, and over the next 3 weeks the EB will be reviewing the final document one last time, and holding final review meetings. Our current timelines are to have our final meeting on July 12th, and a final document to be complete soon after that.

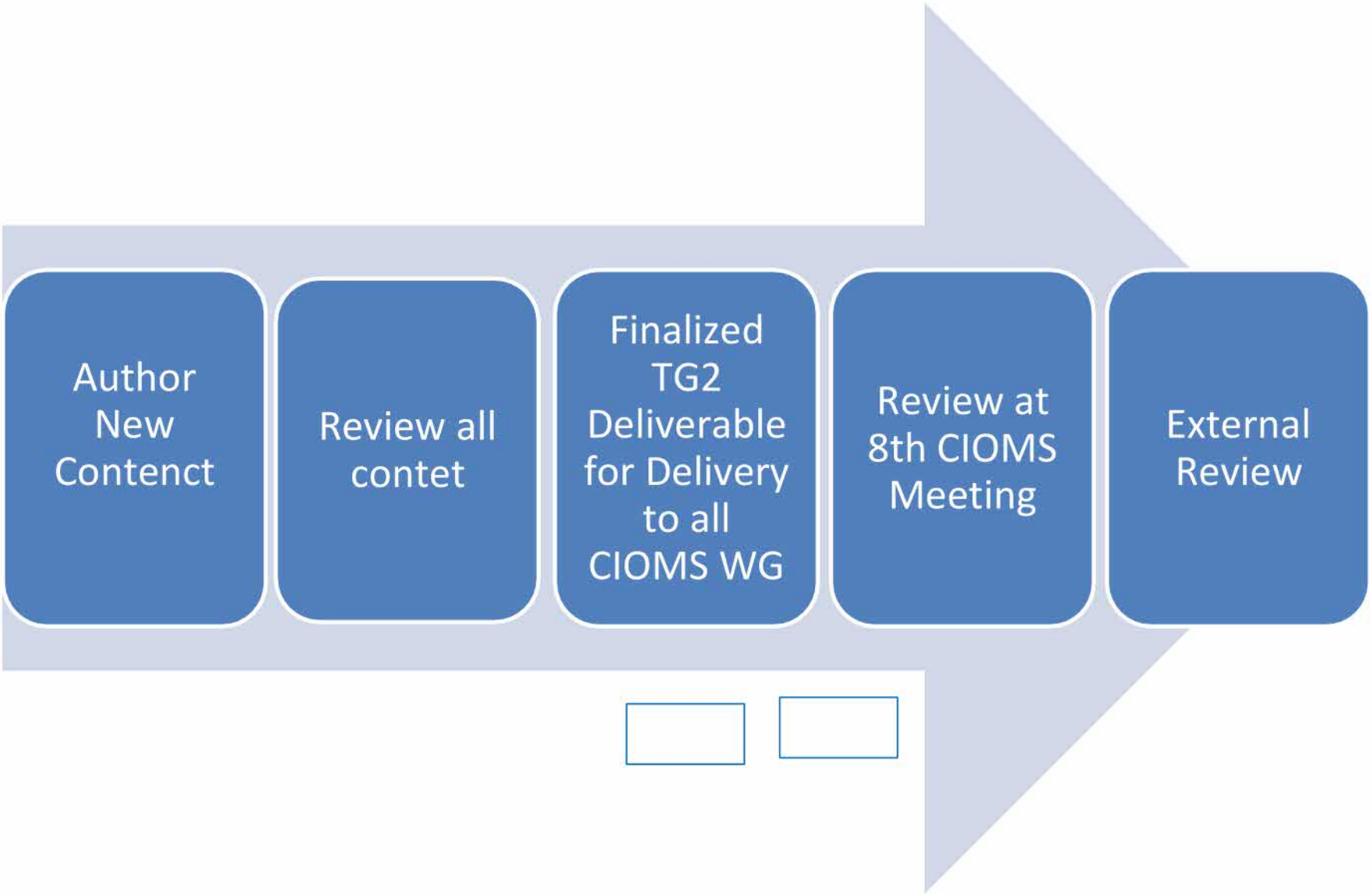
While still undergoing review and update I will say that the document is looking very good: the flow has been much improved, and all sections have been tied together well. The comments from our external experts have been VERY positive, both in terms of the quality of the document, and in their belief it will be of much use and interest to our target audience.

I also wanted to follow up on another issue: you will recall that we had some discussion on how to address information sharing, an issue raised by several WG members. We had a productive meeting on this 3 weeks ago, with active participation from many of you. In the end, we reached consensus that while we agree that this particular issue was not addressed by this WG that it would be best to acknowledge that this work will occur, and that it will likely fall to a future WG. We collected some key thoughts on the issue, and have put them together and will work with CIOMS to consider a symposium or other forum on the subject to move it forward. We also aligned around the decision to NOT discuss

Business Plan TG2 – 21 September 2015

	Lead	Actions	Owner	Timelines
Introduction to TG2		Algorithm:RACI: Benefit Risk Discussion	SteveSteveRob/Ashley	Write by Nov 1Review Nov 23Dec 18th
Chap 1When is additional study/action necessary at introduction?	Steve	Hard Review from TG2Consolidate CommentFinalize (last review)	Steven	Nov 1Nov 23Dec 18
Chap 2What tools can be used for additional studies/actions?	Scott	Hard Review from TG2Consolidate CommentFinalize (last review)	Scott	Nov 1Nov 23Dec 18
Chap 3How can a system for active safety surveillance be established ?	Frank	**Before Table 3.3Hard Review from TG2Consolidate CommentFinalize (last review)After Table 3.3:Table 3.3 and section 3.43.5 and 3.6Ethical section**	ScottNovi/IrinaScottRvw: TG2	Nov 1Nov 23Dec 18Write by Nov 1Write by Nov 1Review by Nov 1

TG2 Key steps



TG2 Pending Actions Items

	What	Who	When
	Throughout note new, new to you, and safety issue		
	Beef up work together		
	Write Intro		
	Approve RACI		
	Final Review and Edits of all content		
	Non Public Communication		
	Add resources to be consulted chapter 3		

From: Bailey, Steven R.
Sent: Tue, 28 Jun 2016 16:15:52 +0000
To: Holm Karin;Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: missing references

Karin:

I don't know the history, but the reference to Brian's article should be fine. Not sure it is a statement that actually requires a reference, honestly (it is just sort of a fact, as far as I am concerned). But the reference to the article gives them a source to learn more if desired.

S.

Steven R. Bailey, MD MPH MBA
Vice President, Worldwide Safety and Regulatory
SSRM RU/Vaccines Group Head
Pfizer
Steven.R.Bailey@Pfizer.com
484 865 3670

From: Holm Karin [mailto:holmk@cioms.ch]
Sent: Tuesday, June 28, 2016 12:00 PM
To: Bailey, Steven R.; DeStefano, Frank (fxd1@cdc.gov)
Subject: missing references

Steven and Frank,

I cannot find the references to this even if I go back to Feb 2015. I think it was copied from another document so there were never any actual references behind it.

3.3.1.1. Cohort studies

....There are several automated databases available for pharmacoepidemiologic studies (Ref 12,,1518).

So I wonder if this reference I found, would be okay in its place?

-
Automated databases
The identification of large numbers of patients for cohort studies could be facilitated if data can be derived from large automated databases. There are several automated databases available for pharmacoepidemiological studies. [27]

[27] Strom, B. L. (2012) Overview of Automated Databases in Pharmacoepidemiology, in Pharmacoepidemiology, Fifth Edition (eds B. L. Strom, S. E. Kimmel and S. Hennessy), Wiley-Blackwell, Oxford, UK.
http://onlinelibrary.wiley.com/doi/10.1002/9781119959946.ch11/summary

From: Bailey, Steven R.
Sent: Tue, 15 Dec 2015 16:19:40 +0000
To: Wivel, Ashley E.;Corinne.Jouquelet-Royer@sanofipasteur.com;Destefano, Frank (CDC/OID/NCEZID);Winiecki, Scott (FDA/CBER);holmk@cioms.ch;novilia@biofarma.co.id;(b)(6);Irina.Caplanusi@ema.europa.eu;mimidarko66@yahoo.co.uk;dongduo@cdr.gov.cn;maurec@who.int;Rmenezes@bio.fiocruz.br;(b)(6);Paulo.santos@bio.fiocruz.br;Harry.A.Seifert@gsk.com;sjolinforsbergg@cioms.ch;atebaa@yahoo.fr;Zuber, Patrick (CDC who.int)
Cc: Maroko, Robert;dongduo@cdr-adr.org.cn;董铎;Bailey, Steven R.
Subject: RE: Some Meeting Follow Up
Attachments: CIOMS Manual on Vacccine Active Safety Surveillance All Comments Combined Chapt 1 update srb.docx
Importance: High

All:

In follow up to the below, please find attached a version of our section with an update to Chapter 1. I have gone through the chapter, and made the suggested edits (and dealt with conflicting edits), as well as addressing all comments. The result is a "near final" draft that would be ready for review by the larger CIOMS group when we have all sections updated.

There were a number of comments however, that I was not able/comfortable addressing. A number of them suggested changes contrary to items we have already discussed and agreed on, or would represent a change in the document significantly different from what has been agreed until now. In these cases, I have left comments in, and they will need to be addressed at a team discussion.

If I can, I would suggest the other section authors do the same. Once we have collected all of the sections, we can put them into one document, and all the open questions for team discussion will be in one place. We can then either a) meet ahead of Ghana by telecon to resolve them or b) wait for discussion at Ghana.

My preference would be to try to schedule a telecon in February if the team agrees. That way we can have these items resolved ahead of the next meeting, and make that more productive.

Please let me know your preferences, and I will update our business plan appropriately.

Regards,

Steven.

Steven R. Bailey, MD MPH MBA
Vice President, Worldwide Safety and Regulatory
SSRM RU/Vaccines Group Head
Pfizer
Steven.R.Bailey@Pfizer.com
484 865 3670

From: Guillermo Herrera Taracena
Sent: Wed, 24 Aug 2011 11:43:07 -0500
To: Destefano, Frank (CDC/OID/NCEZID)
Subject: VSD related question

Dear Frank,

I hope this email finds you well. As you have surely heard, narcolepsy is an issue hot in the news for GSK. Global Epidemiology in Brussels is exploring possibilities for a study looking into (b)(4) (b)(4) As we worked in the past with VSD, I decided to first seek for your opinion and depart from there. The Influenza Group at GSK will be visiting the CDC on September 22nd and this could be an opportunity to further explore any alternatives there could be. Let me know and if you prefer, we can talk on the phone at a date and time that is of your convenience.

All the best,

Guillermo Herrera Taracena, MD, MBA
GlaxoSmithKline
Medical Affairs
Director Influenza Vaccines
Tel: 610 787 3267
Mob: 484 682 9153
Fax: 610 787 7055

Here are the key issues for your consideration:

1) For the table: as we agreed, we have removed the superfluous grid lines, and now have just two rows. I have cleaned up the language and formatting as well. And I have made sure it matches our text elsewhere.
   A) Please comment generally on this table, and suggest any further updates
   B) Note specifically: there is some debate around a (b)(4) and where it belongs. I have consulted several sources and I do think it belongs in the middle column (b)(4) (b)(4). Please comment if you disagree
   C) Note there are several comments still in the table. Let us know if you agree or disagree. Esp. note whether you feel these items need to appear in the glossary.

2) For case study 1: There was a lot of discussion around this as well. It is actually related to item 1-B) How do we consider (b)(4). If we do include (b)(4) (b)(4) then we need to update the case study and the text around it. I have done so. Please look at the updated language and comment as you see fit.

Note: if we are not aligned on where (b)(4) belongs, we will need to leave it to the Ed Board, but I am trying to solve this now if we can.

Regards,

Steven.

PS: note: if you feel this is not an area where you have appropriate expertise, and don't want to weigh in, that is fine. But all comments are welcome.

Steven R. Bailey, MD MPH MBA
Vice President, Worldwide Safety and Regulatory
SSRM RU/Vaccines Group Head
Pfizer
Steven.R.Bailey@Pfizer.com
484 865 3670

From: Bailey, Steven R.
Sent: Thu, 1 Dec 2016 20:18:11 +0000
To: Straus, Walter L.;Destefano, Frank (CDC/OID/NCEZID);Holm Karin;'Corinne.Jouquelet-Royer@sanofipasteur.com';Zuber, Patrick (CDC who.int);Rago Lembit;Paulo.santos@bio.fiocruz.br;novilia@biofarma.co.id;Irina.Caplanusi@ema.europa.eu;Winiecki, Scott (FDA/CBER);maurec@who.int;Priya.Bahri@ema.europa.eu
Cc: Bailey, Steven R.
Subject: Two Items for your Consideration and Comment
Attachments: CIOMS guide AVSS_1_Dec srb Table 2 Only.docx

All:

We continue to work on the document to move things forward (Karin has been doing the heavy lifting of incorporating all the additional comments we have been receiving). She continues to work on this.

She and I met this morning to try to resolve as much as we can prior to the editorial board meeting on the 15th of December. There were two items that I was asked to resolve after our last meeting that we need input on:

(b)(4)

I have taken a stab at resolving both of these, and my proposals are attached (it is a focused excerpt from the manual: after we resolve we will drop it back in).

Here are the key issues for your consideration:

1) For the table: as we agreed, we have removed the superfluous grid lines, and now have just two rows. I have cleaned up the language and formatting as well. And I have made sure it matches our text elsewhere.
   A) Please comment generally on this table, and suggest any further updates
   B) Note specifically: there is some debate around (b)(4) and where it belongs. I have consulted several sources and I do think it belongs in the middle column (b)(4) (b)(4) Please comment if you disagree
   C) Note there are several comments still in the table. Let us know if you agree or disagree. Esp. note whether you feel these items need to appear in the glossary.

2) For case study 1: There was a lot of discussion around this as well. It is actually related to item 1-B) How do we consider (b)(4) If we do include (b)(4) (b)(4) then we need to update the case study and the text around it. I have done so. Please look at the updated language and comment as you see fit.

Note: if we are not aligned on where (b)(4) belongs, we will need to leave it to the Ed Board, but I am trying to solve this now if we can.

Regards,

From: Cristina Masseria
Sent: Fri, 10 Jan 2014 18:20:15 +0000
To: Liang, Jennifer L. (CDC/OID/NCIRD);Shanthy Krishnarajah
Cc: Cho, Bo-Hyun (CDC/OID/NCIRD);Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Agenda for January meeting

Hi Jennifer,

I was just about to send you an email with the updated agenda.

We plan to present the results of recently completed studies

- (b)(4)
-

We would also like to discuss with you and your colleagues studies that we plan to conduct in 2014 and 2015:
US plan:

- (b)(4)
-
-

Brief summary of the globa (b)(4)

CDC
Updates on health economics/epidemiology studies.

Finally, for the last part of the meeting we would like to discuss the revaccination model.

It will be good to have a chance to discuss with Conrad Quinn.

From 1-2 we will be meeting with Dr De Stefano and his colleagues to discuss studies (b)(4) (b)(4). As Dr De Stefano said, you are welcome to attend if still available.

Best,
Cristina

Cristina Masseria, PhD
GlaxoSmithKline
US Health Outcomes and Medical Policy - Vaccines
Phone: +1.215.751.4960