From: Destefano, Frank (CDC/OID/NCEZID)
Sent: 19 Mar 2015 16:13:26 +0000
To: 'Harry.A.Seifert@gsk.com'
Subject: Re: dinner

Dinner near the hotel sounds good to me. Shall we meet in the lobby at 7 pm?

From: Harry Seifert [mailto:Harry.A.Seifert@gsk.com]
Sent: Thursday, March 19, 2015 05:07 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Subject: dinner

Steve proposed that we take a taxi and meet home near the old town (where we had dinner last night) at around 7:00. We had not fixed a meeting or dinner location.
I am starting to crash, so I could easily be convinced to stay closer to our hotel and get dinner someplace very nearby – or even in the hotel restaurant. Let me know what you'd prefer and we'll go from there. I am going to take a shower and will check my email thereafter. Or, you can text me at (b)(6) whatever is easiest for you.
Harry

From: Straus, Walter L.
Sent: 5 Feb 2015 11:36:42 -0500
To: Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Intro Frank Destefano and Walter Straus

That's great. Would you like for me to call you (if so, what#)? Otherwise, my # is (b)(6)

Walter

Walter L. Straus, MD, MPH, FCPP, FACP Executive Director, Global Director for Scientific Affairs / Merck Research Laboratories, Merck & Co., Inc., 351 North Sumneytown Pike, North Wales, PA 19454 / Tel: 267-305-7143 /Fax: 215-616-1095
Assistant: Betsy Panacio betsy_panacio@@merck.com Tel: 267-305-2541

-----Original Message-----
From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Thursday, February 05, 2015 8:49 AM
To: Straus, Walter L.
Subject: RE: Intro Frank Destefano and Walter Straus

Hi Walter,
I am available on 2/11 at 4pm.
Frank

-----Original Message-----
From: Straus, Walter L. [mailto:walter_straus@merck.com]
Sent: Tuesday, February 03, 2015 2:45 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Intro Frank Destefano and Walter Straus

Frank,
Do you have a few minutes any of the dates: 2/10, 11 or 12 after 3 PM?

Walter

Walter L. Straus, MD, MPH, FCPP, FACP Executive Director, Global Director for Scientific Affairs / Merck Research Laboratories, Merck & Co., Inc., 351 North Sumneytown Pike, North Wales, PA 19454 / Tel: 267-305-7143 /Fax: 215-616-1095
Assistant: Betsy Panacio betsy_panacio@@merck.com Tel: 267-305-2541

-----Original Message-----
From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Tuesday, February 03, 2015 10:52 AM
To: Straus, Walter L.
Subject: RE: Intro Frank Destefano and Walter Straus

CISA is a formal project. It conducts clinical research in addition to providing consultation on individual cases. I'd be happy to discuss further if you like.

-----Original Message-----
From: Straus, Walter L. [mailto:walter_straus@merck.com]

Sent: Tuesday, February 03, 2015 8:37 AM
To: Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Intro Frank Destefano and Walter Straus

Hi Frank,
I've had a chance to look at the slides. It's a tremendous help.
One question I had concerned the CISA project. Is this a formal project, or simply a mechanism for CDC to engage academicians, in an ad hoc manner, on consultations when questions arise regarding safety of a vaccine?
If easiest, can we find a few minutes to chat by phone?
Again, MANY thanks. I will, of course, acknowledge you in the presentation.
Best,

Walter

Walter L. Straus, MD, MPH, FCPP, FACP Executive Director, Global Director for Scientific Affairs / Merck Research Laboratories, Merck & Co., Inc., 351 North Sumneytown Pike, North Wales, PA 19454 / Tel: 267-305-7143 /Fax: 215-616-1095
Assistant: Betsy Panacio betsy_panacio@@merck.com Tel: 267-305-2541

-----Original Message-----
From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Monday, February 02, 2015 4:29 PM
To: Straus, Walter L.
Subject: RE: Intro Frank Destefano and Walter Straus

Hi Walter,
Good to hear from you. Attached are slides from a general vaccine safety talk that I gave at the NFID Vaccinology course recently. You can borrow at will.
Best regards,
Frank

-----Original Message-----
From: Straus, Walter L. [mailto:walter_straus@merck.com]
Sent: Monday, February 02, 2015 3:42 PM
To: Chen, Robert (Bob) (CDC/OID/NCHHSTP)
Cc: Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Intro Frank Destefano and Walter Straus

Thanks, Bob.
I've known Frank for years, but hadn't had a chance to speak recently. Any publicly available slides re VAERS/VSD would be great. We can also easily chat by phone.
Many thanks to both of you.

Walter

Walter L. Straus, MD, MPH, FCPP, FACP Executive Director, Global Director for Scientific Affairs / Merck Research Laboratories, Merck & Co., Inc., 351 North Sumneytown Pike, North Wales, PA 19454 / Tel: 267-305-7143 /Fax: 215-616-1095
Assistant: Betsy Panacio betsy_panacio@@merck.com Tel: 267-305-2541

-----Original Message-----
From: Chen, Robert (Bob) (CDC/OID/NCHHSTP) [mailto:rtc1@cdc.gov]
Sent: Monday, February 02, 2015 3:20 PM
To: Straus, Walter L.
Cc: Destefano, Frank (CDC/OID/NCEZID)
Subject: Intro Frank Destefano and Walter Straus

Walter,

Good to chat. The recent review paper on VSD is PMID: 25108215. There is one on VAERS too but it's still under peer review. So PMID: 15071280 probably best stand in in the interim.

Frank,

Walter Straus (EIS 1990) now at Merck is giving a talk and was wondering if CDC has slides re: VAERS and VSD that he can borrow.

Bob

-----Original Message-----
From: Straus, Walter L. [mailto:walter_straus@merck.com]
Sent: Monday, February 02, 2015 1:47 PM
To: Chen, Robert (Bob) (CDC/OID/NCHHSTP)
Subject: RE: Chat next week?

Bob,
Thanks for this, and for the call.

Best,

Walter

Walter L. Straus, MD, MPH, FCPP, FACP Executive Director, Global Director for Scientific Affairs / Merck Research Laboratories, Merck & Co., Inc., 351 North Sumneytown Pike, North Wales, PA 19454 / Tel: 267-305-7143 /Fax: 215-616-1095
Assistant: Betsy Panacio betsy_panacio@@merck.com Tel: 267-305-2541

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I'm following up on Bruce's email regarding the CDC-sponsored analysis of pandemic vaccination and narcolepsy in the VSD.
As you certainly know, GSK is supporting a study in Canada, as well as interacting with the European Medicines Agency to explore further avenues to assess the narcolepsy signal. Options include implementing studies in settings where a non-adjuvanted pandemic vaccine was used; assessing the impact of other vaccines (e.g. seasonal TIV) or natural infection (using proxies such as records of influenza-like illness, lab-confirmed infection, or surveillance data on circulating strains).
The study in the VSD provides an opportunity to touch these different aspects. This type of research would supplement existing independent initiatives (such as the ECDC sponsored multi-country VAESCO study in Europe) and could shed light on the role of the vaccine antigen vs. virus infection vs. the adjuvant.
That said, small numbers and need for in-depth case adjudication are indeed a challenge! We have regular contacts with Emmanuel Mignot, sleep expert from the Stanford University Center for narcolepsy; he could probably provide advice (he recently mentioned having heard anecdotal evidence of increased incidence of diagnosis in children in the US...).
In the context of regulatory discussions on the submission of future adjuvanted (pre)pandemic vaccines in the US, we also feel that the VSD analysis could contribute addressing a mutually important question.
We'd be happy to set up a teleconference to share our experience so far and discuss how we can help, as well as discuss ongoing and planned research (I heard that VAESCO are considering extending the study to include countries outside of Europe, incl. the US...)..
Best regards,
Catherine

Catherine Cohet, PhD
Senior Epidemiologist, Pandemic Vaccines
GlaxoSmithKline Biologicals | Global Vaccine Development | Avenue Fleming 20 | 1300 Wavre | Belgium
☎ +32 1085 9084 (office) | +32 488 157 317 (mobile)
catherine.cohet@gskbio.com

From: Bruce Innis
Sent: Tuesday 20 December 2011 19:51
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: David Vaughn; Huebner, Robert (OS); Stuart Burstin; Catherine Cohet (Biologicals, BE)
Subject: RE: Question from GSK Biologicals

Dear Frank:
Tx for the prompt reply. I use this email to introduce you to Catherine Cohet, GSK's epidemiologist in Belgium for the pandemic influenza vaccine project team. Catherine, who works for Vivek Shinde (ex-CDC) whom you might know, may wish to f/u with you in early 2012.
Best wishes,
Bruce

Bruce L. Innis, MD
Vaccines for Influenza, MMR, Varicella and Dengue
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GSK Biologicals
King of Prussia, PA, USA
TEL: +1 610 787 3105/3110
MOBILE: +1 484 802 6098
bruce.2.innis@gsk.com

From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Tuesday, December 20, 2011 1:36 PM
To: Bruce Innis

Cc: David Vaughn; Huebner, Robert (OS); Stuart Burstin
Subject: RE: Question from GSK Biologicals

Bruce,

Yes, we are conducting an exploratory analysis of narcolepsy and the H1N1 vaccine. Thus far, we only have data from computerized diagnostic codes and are in the process of trying to validate those codes by medical chart reviews. I suspect that we may have too few cases to draw any firm conclusions.

I hope this helps,

Frank

Frank DeStefano, MD, MPH
Director
Immunization Safety Office
MS D-26
Centers for Disease Control and Prevention
1600 Clifton Rd., NE
Atlanta, GA 30333

From: Bruce Innis [mailto:Bruce.2.Innis@gsk.com]
Sent: Tuesday, December 20, 2011 11:54 AM
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: David Vaughn; Huebner, Robert (OS); Stuart Burstin
Subject: Question from GSK Biologicals

Dear Frank:

Hi. I am writing to f/u on an email that you sent to Guillermo Herrera Taracena on 25 Aug (see below in red text). May I ask if CDC plans have advanced to explore a potential link between narcolepsy and H1N1 infection or vaccination? GSK has briefly discussed the potential value of such an investigation with Robert Heubner from HHS/BARDA in the context of our contract with HHS/BARDA to develop adjuvanted pandemic vaccines.

(From Frank Destefano to Guillermo): Yes, VSD plans to do an analysis of narcolepsy. The first step will be to determine how many cases there may be. Narcolepsy is rare and VSD may not have sufficient cases to do any meaningful analysis. Unfortunately, I will be out of the country on September 22nd and will miss the opportunity to see you then. I hope all is well.

With best wishes,

Bruce

Bruce L. Innis, MD
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VP, Global Vaccine Development
GSK Biologicals
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TEL: +1 610 787 3105/3110
MOBILE: (b)(6)
bruce.2.innis@gsk.com

From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Tuesday, January 07, 2014 3:53 PM
To: Shanthy Krishnarajah; Broder, Karen (CDC/OID/NCEZID)
Cc: Cristina Masseria; Leonard Silverstein; Weinbaum, Cindy (CDC/OID/NCEZID)
Subject: RE: Safety of Boostrix during pregnancy

Dear Ms. Krishnarajah,

Thank you again for your request for consultation and for your patience in waiting for our response. We have a mutual interest in gaining more data on the safety of Tdap vaccines administered to pregnant women. Dr. Broder and I could be available to meet with GSK colleagues to discuss maternal Tdap safety issues on January 22 when you are at CDC. Dr. Cindy Weinbaum, in the Division of Healthcare Quality Promotion (copied here), will follow-up with you in the near future on the logistics for the safety meeting. We can further discuss your other questions during that time.

Best wishes for the New Year,

Frank DeStefano, MD, MPH
Director
Immunization Safety Office
Centers for Disease Control and Prevention
Atlanta, GA

From: Shanthy Krishnarajah [mailto:girishanthy.x.krishnarajah@gsk.com]
Sent: Monday, December 16, 2013 10:15 PM
To: Destefano, Frank (CDC/OID/NCEZID); Broder, Karen (CDC/OID/NCEZID)
Cc: Cristina Masseria; Leonard Silverstein
Subject: RE: Safety of Boostrix during pregnancy

Dear Dr. Destefano and Dr. Broder,

Thank you for your time on Dec 5th call.

Pursuant to teleconference, we wanted to follow up on some specific questions we have on the potential safety study using Boostrix among Pregnant women that we are currently evaluating. I am not sure if I mentioned that GSK is interested in including the results of the study proposed by GSK for safety and regulatory purposes.

In addition I wanted to follow up on the following questions

a/ Are you able to recommend other sites than Duke and Vanderbilt which would be able to recruit pregnant women vaccinated with Boostrix that are part of the CISA network?

b/ Are there any lessons learnt from implementing a safety study around pregnant women you are currently planning

c/ How are you adjusting for women who would have received flu vaccine when looking at adverse events

We are still in the process of drafting a concept design and would like to see if you would be open to reviewing the protocol.

And finally we are having a face to face meeting with Tom and his colleagues the morning of Jan 22nd. Let us know if you would also be open to meeting us that day.

Thanks very much and Happy Holidays

Shanthy Krishnarajah, MPH, MBA/MS
Head US HO/Epidemiology Vaccines
USHO and MP
Work Tel: 215 751-3267
Cell : (b)(6)
Pls Note my new office number

From: Kuter, Barbara J.
Sent: 28 Mar 2014 15:50:21 -0400
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: Wharton, Melinda (CDC/OID/NCIRD)
Subject: RE: HPV Vaccine - Japan

Frank,

Thanks for these numbers - this is very helpful. Would it be appropriate to compare the reporting rate of fibromyalgia in VAERS (based on doses distributed) to a background rate of fibromyalgia in this age group (with the appropriate caveats)? If so, what background rate would you use, please?

And by any chance do you know the age range for the 41 cases reported?

Thanks again,

Barb

-----Original Message-----
From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Friday, March 28, 2014 12:57 PM
To: Kuter, Barbara J.
Cc: Wharton, Melinda (CDC/OID/NCIRD)
Subject: RE: HPV Vaccine - Japan

The HPV/Fibromyalgia search includes all reports in VAERS from the time HPV4 vaccine was originally licensed (6/8/06) to reports received and processed (some reports received may not have been processed/entered yet) as of 3/27/14.

From the time of HPV4 vaccine licensure on 6/8/06 to 3/27/14, VAERS has received and processed a total of 27,300 US primary reports for HPV2, HPV4 or HPVx(HPV brand unknown) when given alone or in combination with other vaccines; 1971 (7.2%) were serious reports and 25,329 (92.78%) were non serious. A serious report is one in which at least one of the following was reported: death, life threatening illness, hospitalization, prolongation of an existing hospitalization or permanent disability.

From 6/8/06 to 3/27/14, VAERS has received and processed a total of 219,447 US primary reports after ALL vaccines. Of those 10,659 (4.86%) were serious and 208,788 (95.14%) were non serious.

-----Original Message-----
From: Kuter, Barbara J. [mailto:barbara_kuter@merck.com]
Sent: Friday, March 28, 2014 12:05 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: Wharton, Melinda (CDC/OID/NCIRD)
Subject: RE: HPV Vaccine - Japan

Thanks, Frank, for the rapid response. I assume this search covered the period from 2006 to date. Can you please remind me of the total number of VAERS reports received over that period?

Barb

-----Original Message-----
From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Friday, March 28, 2014 9:59 AM
To: Kuter, Barbara J.
Cc: Wharton, Melinda (CDC/OID/NCIRD)

Subject: RE: HPV Vaccine - Japan

Barb,
We searched VAERS for US primary reports coded as "FIBROMYALGIA" after HPV2, HPV4 or HPVx(HPV brand unknown) when given alone or in combination with other vaccines. VAERS contains 41 reports. Of those, 33 were for cases in which HPV4 was the only vaccine administered. Of the 41 reports, 25 were serious. Among the 25 serious reports, 5 were reported as a life threatening illness, 12 required hospitalization and 8 resulted in permanent disability.

I hope this helps,
Frank

-----Original Message-----
From: Kuter, Barbara J. [mailto:barbara_kuter@merck.com]
Sent: Thursday, March 27, 2014 2:40 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: Wharton, Melinda (CDC/OID/NCIRD)
Subject: RE: HPV Vaccine - Japan

Frank,

Thanks for your rapid response. If you could take a quick look at this in VAERS, that would be helpful. Of course, we recognize the limitations of doing so.

Thanks again,

Barb

-----Original Message-----
From: Destefano, Frank (CDC/OID/NCEZID) [mailto:fxd1@cdc.gov]
Sent: Thursday, March 27, 2014 1:51 PM
To: Kuter, Barbara J.; Wharton, Melinda (CDC/OID/NCIRD)
Subject: RE: HPV Vaccine - Japan

Barb,
We have not been contacted about this. We also are not aware of any literature or other data on HPV vaccine and CTD's. We have not looked at fibromyalgia in VSD or VAERS. This is a complex diagnosis and does not lend itself to a quick analysis in either system, but for what it would be worth (which may be little) we could take a look at reports submitted to VAERS.
Thanks for bringing this to our attention, Frank

-----Original Message-----
From: Kuter, Barbara J. [mailto:barbara_kuter@merck.com]
Sent: Thursday, March 27, 2014 11:38 AM
To: Wharton, Melinda (CDC/OID/NCIRD); Destefano, Frank (CDC/OID/NCEZID)
Subject: HPV Vaccine - Japan

Melinda and Frank,

We just received the attached English translation of a news item from Japan describing a preliminary study of patients with connective tissue disorder (rheumatoid arthritis and fibromyalgia) and their use of HPV vaccines. The information is based on a presentation made at a health seminar by a local investigator from the Japanese College of Fibromyalgia (JCFI), Tokyo Medical University. The JCFI has asked MHLW to conduct further research in this area.

We will be looking at our own pre & postlicensure safety data to address this question, but thought it would be helpful to find out if CDC has also been contacted to provide any data. Can you please tell me if you have looked at fibromyalgia in either VAERS or VSD or might be able to do so? We have not found any evaluation of this particular AE in the literature.

Any information you can share with us would be much appreciated.

Thanks.

Barb

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From: David Vaughn
Sent: 7 Nov 2014 18:37:08 +0000
To: Broder, Karen (CDC/OID/NCEZID)
Cc: Gronostaj, Michael (CDC/OPHSS/CSELS/DSEPD);Clark, Thomas A. (CDC/ONDIEH/NCCDPHP);Destefano, Frank (CDC/OID/NCEZID);François P Roman;Fernanda Tavares Da Silva;Valentina Attanasi
Subject: RE: Ebola vaccine pharmacovigilence
Attachments: 202091 (EBOLA Z CHAD3-005) concept protocol (07-NOV-2014) clean.docx

Karen,
Attached you should find the Phase 2 study protocol draft for adults; today's version. It should not be necessary to exceed (or even match) the safety surveillance found in this study for your Phase 3.
Tom Clark, Have you received a version of the NIH Phase 3 protocol from Barney Graham?
David.

From: Broder, Karen (CDC/OID/NCEZID) [mailto:krb2@cdc.gov]
Sent: Thursday, November 06, 2014 10:14 AM
To: David Vaughn
Cc: Gronostaj, Michael (CDC/OID/NCEZID); Clark, Thomas A. (CDC/OID/NCIRD); Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Ebola vaccine pharmacovigilence

Hi David,
I hope you are well. We are working on the vaccine safety sections and forms for the draft CDC Expanded Access protocol for Tom Clark's team. The sections are still evolving as we get input from the staff in the field.
We have been trying to harmonize safety definitions, to the extent practical, with the last version of the NIH protocol we have (Oct 24). Is this the most recent version? Also do you have any of the vaccine safety forms from this study that could be shared with us?
Lastly, we are wondering if it might be helpful to have a short call with you regarding the materials we are developing for safety monitoring, perhaps tomorrow Friday November 7, to get some input?
Thanks,
Karen

From: David Vaughn [mailto:david.w.vaughn@gsk.com]
Sent: Friday, October 31, 2014 7:06 AM
To: Broder, Karen (CDC/OID/NCEZID)
Cc: Iris De Ryck
Subject: Ebola vaccine pharmacovigilence

Karen,
Do have time next Tuesday or Wednesday to discuss post-marketing (or emergency use) PV in Africa? As the MAH for an Ebola vaccine, we need a Risk Management Plan which includes a PV plan for countries where the vaccine will be used. Capacity building in the affected countries would be challenging. Stand-alone PV studies could be done using sentinel sites. This would all be separate from Phase 3 activities. There is a possibility that GSK will seek EU funding for such efforts and we would like to have an informal discussion with you about what such an effort might look like. If the NIH/GSK vaccine is safe and effective, good PV is of importance to all (including BARDA, CDC, NIH, and DoD) as a bad PV program could derail a good vaccine or identify late a signal that reflects a real problem.
Iris is our clinical safety lead for Ebola vaccine. We are both available Tuesday, 4 November from 0800-0900 and from 1030-1100 and Wednesday 0900-1000 and after 1100 (Iris, recall that Europe falls back on Sunday and so CET is just 5 hours ahead of Philly and Atlanta for a couple weeks).
Thanks, David.
David W. Vaughn, MD, MPH
Head, External R&D, North America

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From: Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 8 Apr 2019 13:31:22 +0000
To: Straus, Walter L.
Subject: RE: Brighton / Sentinel-PRISM question

Hi Walter,
Sorry, I do not know about use of BC definitions in Sentinel. I am hoping to be able to attend ICPE and look forward to seeing you there.
Regards,
Frank

Frank DeStefano, MD, MPH

From: Straus, Walter L. (b)(6)
Sent: Monday, April 8, 2019 8:59 AM
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>
Subject: Brighton / Sentinel-PRISM question

Hi Frank –
I hope all is well with family and work.
I have an upcoming presentation on an industry perspective of Sentinel, and I am wondering whether you are aware of any discussions/plans related to applying Brighton classifications for Sentinel/PRISM activities.
Looking forward to seeing you soon (Phila – ICPE?).
Best,

Walter

Walter Straus, MD, MPH | Associate Vice-President | Therapeutic Area Head for Vaccines and Infectious Diseases | Clinical Safety & Risk Management | Merck Research Laboratories |351 N Sumneytown Pike | UG3C-54 | PO Box 1000 | N Wales, PA 18954

T: (b)(6)
Assistant: Jane Detweile (b)(6)