
From: Hsu, Irene [JANUS]
Sent: Tuesday, October 22, 2002 3:15 PM
To: Deloria, Carmen [JANUS]; Reyes-Harde, Magali [JANUS]; Lin, Joseph [JANUS]
Subject: FW: Follow-Up National Child and Adolescent Advisory Board Justification Document

Importance: High



Nov 02 Business
Justification....

-----Original Message-----

From: Hsu, Irene [JANUS]
Sent: Tuesday, October 22, 2002 11:07 AM
To: Mallegol, David [JANUS]; Chester, Michael [JANUS]
Subject: RE: Follow-Up National Child and Adolescent Advisory Board Justification Document
Importance: High

Dave,

Here's the information:

The June meeting was held on June 14, 2002 (1-day meeting, from 7:00 am -- 4:30 pm)

12 KOLs (national advisors) attended

honorarium: \$2500 each

Key issue presented: NCBRF item analysis, weight gain and prolactin data from CDMR datasets

Key issue discussed: Advisors provided specific recommendations on the re-analysis of these datasets to ensure that the data are presented in a clinically meaningful way to clinicians, eg. looking at outliers in weight gain, prolactin elevation (vs. group mean data as presented), whether there're any correlation of prolactin to weight gain, growth and development. The advisors urged us to complete these re-analysis as soon as possible as the safety information can be very reassuring for clinicians.

Carmen closed the meeting, and informed the advisors that we will get back to work on the re-analysis and share the findings with them when we convene them again in 2003. The advisors voiced their concerns re: 1-yr later, and wanted to re-convene before year's end.

Our clinical team had conducted these re-analysis, and we want to re-convene the same group to help us interpret the findings from these re-analysis. The group (Magali, Carmen, Gahan Pandina) discussed, and we believe this is an opportune time to convene the group (potential filing with RUPP datasets, post-AACAP), and would like to have this meeting before the holidays (in mid-late November).

As these are our top-tier KOLs (Joe Biederman, Peter Jensen, Gabrielle Carlson, etc.), we plan to offer \$2500 as honorarium for the 1-day meeting (with arrivals the day prior).

Please let me know if I can answer any other questions that you may have. Attached please find the business justification document.

Thanks,
Irene
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-----Original Message-----

From: Mallegol, David [JANUS]
Sent: Tuesday, October 22, 2002 9:47 AM
To: Hsu, Irene [JANUS]
Subject: RE: Follow-Up National Child and Adolescent Advisory Board Justification Document

Irene, I spoke with legal on this idea of a follow up meeting. We need further discussion on this idea. Please include Mike Chester and myself. Dave M.

-----Original Message-----

From: Hsu, Irene [JANUS]
Sent: Monday, October 21, 2002 11:52 PM
To: Mallegol, David [JANUS]
Cc: Lin, Joseph [JANUS]
Subject: Follow-Up National Child and Adolescent Advisory Board Justification Document
Importance: High

Dear Dave,

Sorry to do this via email. I've been traveling and will be for the next few weeks, and so is Joe Lin (Joe is the new Product Director for Child and Adolescent in New Business, with Carmen). We want to conduct a follow-up meeting to the June National Ad Board -- the advisors recommended that we conduct further re-analysis of our CDMR datasets, and convened the advisors together later this year to review the findings of the re-analysis, as they would like to see us get some of these data published.

We'd like to have this follow-up national advisory board meeting before year's end (in mid-late November), with 12-15 national advisors. The business justification document is attached. Please review and let me know any comments at your earliest convenience, as time is of the essence.

Thanks Dave.

Look forward to hearing from you.

Best,
Irene

<< File: Nov 02 Business Justification.doc >>

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