## **RE: Maddie's vaccination record.**

Frenck, Robert <Robert.Frenck@cchmc.org> Sat 6/12/2021 9:20 PM To: 'Patrick deGaray' Cc Buschle, Kristen <Kristen Buschle@cchmc org>; Stephanie de Garay < Hi Mr deGaray,

The reporting line I mentioned is the one that we are asked to follow.

VAERS is an open system and anyone my report an event. It doesn't have to be a doctor making the report.

VAERS does check against reports to the FDA as they don't want to double count an event.

**Bob Frenck** 

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Dr Frenck,

If that is the case you should still be able to get the tracking number. Also you should have a list of the side effects/adverse reactions you supplied to them, we would like a copy/list of them. We don't want duplicate your submission, but we want to make sure these items are reported.

Thank you,

Patrick

On Jun 11, 2021, at 8:47 AM, Frenck, Robert <<u>Robert.Frenck@cchmc.org</u>> wrote:

Mr De Garay,

Our chain of reporting is to the FDA through the Sponsor.

**Bob Frenck** 

From: Patrick deGaray [mailto] Sent: Thursday, June 10, 2021 8:30 PM To: Buschle, Kristen <<u>Kristen.Buschle@cchmc.org</u>> Cc: Stephanie de Garay < Subject: Re: Maddie's vaccination record.

>; Frenck, Robert <<u>Robert.Frenck@cchmc.org</u>>

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## Kristen,

Sorry to bother you again but could you send the VAERS ID confirmation number along with all the symptoms side effects you submitted to them.

## Patrick

On Jun 10, 2021, at 5:32 PM, Buschle, Kristen <<u>Kristen.Buschle@cchmc.org</u>> wrote:

Hi Patrick, Yes, all of Maddie's symptoms have been reported to the FDA.

Kri ten

Kristen Buschle, MSN, APRN, FNP-C, CCRC, CPN Nur e Practitioner Gamble Program for Clinical Studie Division of Infectious Diseases Cincinnati Children's 3333 Burnet Avenue, MCL 6014, Cincinnati, OH 45229 Work 513 636 8450 Fax: 513-636-7680

From: Patrick deGaray [mailto Sent: Tuesday, June 08, 2021 8:44 PM To: Buschle, Kristen <<u>Kristen.Buschle@cchmc.org</u>> Cc: Stephanie de Garay Subject: Re: Maddie's vaccination record.

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Kristen,

Just want to confirm that all the side effects that we have communicated to both you and the Gamble team since January 2021 have been reported to the CDC. With everything we went through we wanted to be sure the info has been reported to cdc VAERS reporting.

Patrick

On Jun 1, 2021, at 2:47 PM, Buschle, Kristen Kristen Buschle@cchmc org wrote

Hi Patrick,

I am so sorry about that. Yes, we will send you Maddie's corrected card, a well a ''

Kristen

Kristen Buschle, MSN, APRN, FNP C, CCRC, CPN Nurse Practitioner, Gamble Program for Clinical Studies Divi ion of Infectiou Di ease Cincinnati Children's 3333 Burnet Avenue, MCL 6014, Cincinnati, OH 45229 Work: 513-636-8450 Fax 513 636 7680

From: Patrick deGaray [mailto] Sent: Saturday, May 29, 2021 2 21 PM To: Buschle, Kristen <<u>Kristen.Buschle@cchmc.org</u>> Cc: Stephanie de Garay < Subject: Maddie's vaccination record.

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Kristen,

We received the vaccination record for Maddie, but there is no date listed for the 2nd hot Would you lea e correct thi and end the vaccine record for as well.

Thank you,