

From: [REDACTED]
To: [REDACTED]
CC: [REDACTED]
Subject: RE: data for finasteride query
Date: 28.04.2022 13:40:11 (+02:00)

Hi [REDACTED]

See attached results for dutasteride. There are [REDACTED] reports within the Suicide/Self injury SMQ and [REDACTED] reports with the narrative terms post dutasteride syndrome/post- dutasteride syndrome/PDS.

Thanks,

[REDACTED]

From: [REDACTED]
Sent: 27 April 2022 16:42
To: [REDACTED]
Cc: [REDACTED]
Subject: FW: data for finasteride query

Hi [REDACTED]

Would it be easy to re-run this query for dutasteride? I have had a request from a patient regarding dutasteride now

Not sure if [REDACTED] is off?

Best regards

[REDACTED]

From: [REDACTED]
Sent: 08 March 2022 12:33
To: [REDACTED]
Subject: RE: data for finasteride query

Hi [REDACTED]

See attached spreadsheet with this data – one line listing on each tab.

Happy to discuss if you have any questions or need anything else.

Thanks,

[REDACTED]

From: [REDACTED]
Sent: 08 March 2022 10:08
To: [REDACTED] >
Subject: RE: data for finasteride query

Hi [REDACTED]

That's a good approach I think.

Many thanks

█

From: █

Sent: 08 March 2022 09:56

To: █

Cc: █

Subject: FW: data for finasteride query

Hi █

I'm just looking at your request for data below – just wanted to agree on the search strategy before I extract the data. I was thinking to extract all finasteride reports in the Suicide/Self injury SMQ and run a separate search of all finasteride reports and the narrative terms post finasteride syndrome/post-finasteride syndrome/PFS?

I'll extract line listings with initial date received so you'll be able to see the frequency of reports over time.

Let me know if you agree this should capture all the cases of interest, happy to discuss.

Thanks,

█

From: █ >

Sent: 08 March 2022 09:38

To: █

Cc: █; Ord, Kathryn <Kathryn.Ord@mhra.gov.uk>; █

Subject: RE: data for finasteride query

Hi █

Thanks for picking this up at such short notice, please see below request from █ for Finasteride data relating to a signal for post finasteride syndrome.

Thanks,

█

From: Signal Management █

Sent: 08 March 2022 08:39

To: █

█ Ord, Kathryn <Kathryn.Ord@mhra.gov.uk>; Signal Management

Subject: RE: data for finasteride query

Hi █

Thanks for sending this over, general YC data requests like this usually go through █ o allocate out to the wider PSM team – so I am just copying in █ as █ is not very well today.

If you have specific queries/data requests that concern signal information, such as pre-existing signal assessment case folders/signal assessment work or if we have received notification externally pertaining to a particular signal of interest, these can be directed to the signal team mailbox rather than [REDACTED] – if you're ever unsure, please do not hesitate to ask and we can always re-allocate if needs be.

I hope that helps!

Many thanks,

[REDACTED]

From: [REDACTED]
Sent: 07 March 2022 17:22
To: Signal Management [REDACTED]
Cc: [REDACTED] Ord, Kathryn <Kathryn.Ord@mhra.gov.uk>
Subject: data for finasteride query

Hi [REDACTED] and team

I'm not sure whether this should go out wider than your team (please advise for future purposes) I have received a query on post finasteride syndrome and finasteride 1 mg [Propecia 7 generics] and I thought I would discuss this at Thursdays signal meeting.

I'm afraid I'm a bit rusty with retrieving data these days. Would someone be able to pull out YC reports on post finasteride syndrome (not a term as not a recognised medical condition so will have to be retrieved from the case narrative) and suicidal depression and similar terms since this has been marketed. I'm also interested in the frequency of reporting since we varied the label in 2017. We get queries regarding this from time to time and therefore I wanted to discuss it in order to ensure that I am considering all options and have sight of all the data. Sorry for the short notice. In view of providing a timely response I think I should bring it back this Thursday.

Kind regards & many thanks for your help

[REDACTED]

[REDACTED]

Senior Scientific Assessor
Benefit & Risk Management Group (Unit 1)| Vigilance and Risk Management of Medicines (VRMM)

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