

s 22

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**From:** s 47F  
**Sent:** Tuesday, 30 July 2019 2:29 PM  
**To:** MSAC SECRETARIAT; s 47F  
**Cc:** s 47F ; s 22  
**Subject:** Re: 1342.5 - Clinical Study Report request for MSAC [SEC=OFFICIAL]

Thanks s 22

Noted. I think we have enough

Regards

s 47F

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**From:** MSAC  
**Date:** Tuesday, 30 July 2019 at 1:02 pm  
**To:** s 47F  
**Cc:** s 47F , s 22 , MSAC  
**Subject:** FW: 1342.5 - Clinical Study Report request for MSAC [SEC=OFFICIAL]

Dear s 47F

This is the Applicant's response to the request for the CSR.

Kind Regards

s 22

**From:** s 47F  
**Sent:** Tuesday, 30 July 2019 9:13 AM  
**To:** s 22  
**Cc:** ; MSAC SECRETARIAT  
**Subject:** Re: 1342.5 - Clinical Study Report request for MSAC [SEC=OFFICIAL]

Dear s 47F

We received the following feedback from GHI:

Steve Shak, the Chief Scientific Officer, advises that there is no ECOG detailed internal study report.

The best way to proceed is if MSAC have specific questions about the study, they can contact Joe Sparano and ask him directly. His contact details are:

Joseph A. Sparano, M.D.

Montefiore Albert Einstein College of Medicine

Phone +1 718-904-2555

Email [jsparano@montefiore.org](mailto:jsparano@montefiore.org)

Website <http://www.einstein.yu.edu/faculty/2952/joseph-sparano/>

It would be great if they kept us in the loop so we can follow up if there is any gap in communication.

I hope this is useful.

Yours Sincerely

s 47G

On Mon, 29 Jul 2019 at 11:50, s 22

wrote:

Thanks s 47F

If you could check that with GHI that would be great.

Kind Regards

s 22

MSAC Secretariat

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**Medical Services Technology Section | Office of Health Technology Assessment Branch**

**Technology Assessment and Access Division**

Australian Government Department of Health

PO Box 9848, Canberra ACT 2601, Australia

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**From:** s 47F

**Sent:** Monday, 29 July 2019 11:26 AM

**To:** s 22

**Cc:** 'Vanessa van den Berg' <[vvandenberg@stbiopharma.com](mailto:vvandenberg@stbiopharma.com)>; s 47F  
'Bruce Arthur' <[barthur@stbiopharma.com](mailto:barthur@stbiopharma.com)>; MSAC SECRETARIAT  
<[MSAC.SECRETARIAT@health.gov.au](mailto:MSAC.SECRETARIAT@health.gov.au)>

**Subject:** RE: 1342.5 - Clinical Study Report request for MSAC [SEC=OFFICIAL]

Hi s 22

Unfortunately, we do not have access to the CSR.

The TAILORx trial was not conducted by the applicant<sup>s 47G</sup> the sponsor of the Oncotype DX test (Genomic Health Inc, GHI). Therefore, we only have access to what has been published – which is the Sparano paper and the associated Appendix (which you have with the application).

We will double check overnight with GHI if they have anything more they could provide.

Hope this is OK

Thanks

s 47F

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**From:** s 22

**Sent:** Monday, 29 July 2019 11:01 AM

**To:** s 47F

**Cc:** s 47G

s 47F

MSAC SECRETARIAT

<[MSAC.SECRETARIAT@health.gov.au](mailto:MSAC.SECRETARIAT@health.gov.au)>

**Subject:** 1342.5 - Clinical Study Report request for MSAC [SEC=OFFICIAL]

**Importance:** High

Good Morning s 47F

MSAC has requested a copy of the CSR for TailorX. Would you be able to provide this ASAP?

Kind Regards

s 22

MSAC Secretariat

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**Medical Services Technology Section | Office of Health Technology Assessment Branch**

**Technology Assessment and Access Division**

Australian Government Department of Health

PO Box 9848, Canberra ACT 2601, Australia

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