

Re: PTC596-ONC-007-LMS monthly update | Update

Rance, Mark <mrance@ptcbio.com>

Tue 6/20/2023 2:04 AM

To: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>; Yang, Kanwen <kyang@ptcbio.com>

Cc: Kimberly Green <Kim.Green@claritidox.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>

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Approved

Thanks

Mark

Get [Outlook for iOS](#)

From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>**Sent:** Monday, June 19, 2023 8:36:14 PM**To:** Yang, Kanwen <kyang@ptcbio.com>; Rance, Mark <mrance@ptcbio.com>**Cc:** Kimberly Green <Kim.Green@claritidox.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>**Subject:** [EXTERNAL] Re: PTC596-ONC-007-LMS monthly update | Update

Hi Kanwen,

Thanks for the confirmation. Even if there are no updates, we will still release the record on CT.gov so that the validation date in the system stays current.

[@Rance, Mark](#), Since you do not have access to the Disclose system, I have attached a PDF copy of the protocol registered on CT.gov. Could you please check and confirm your approval?

Thanks!

Warm Regards,
Abhijeet Srivastava
ClaritiDox LLCEmail: Abhijeet.Srivastava@ClaritiDox.com

From: Yang, Kanwen <kyang@ptcbio.com>**Sent:** Monday, June 19, 2023 8:23 PM**To:** Brodie Barnard <Brodie.Barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>**Cc:** Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>**Subject:** RE: PTC596-ONC-007-LMS monthly update | UpdateYou don't often get email from kyang@ptcbio.com. [Learn why this is important](#)

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Then, I don't have any update for the 007 study at this point.

Best,
Kanwen

From: Brodie Barnard <Brodie.Barnard@claritidox.com>
Sent: Monday, June 19, 2023 10:47 AM
To: Yang, Kanwen <kyang@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>
Subject: [EXTERNAL] RE: PTC596-ONC-007-LMS monthly update | Update

Hi Kanwen,

Since the overall recruitment status for the study is listed as "Active, Not Recruiting" the individual site statuses are not shown on the public site.

Kind regards,
Brodie

From: Yang, Kanwen <kyang@ptcbio.com>
Sent: Monday, June 19, 2023 10:32 AM
To: Brodie Barnard <Brodie.Barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>
Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Hi Brodie:

Nice to meet you and look forward to working with you as well!

I don't see the recruiting status of those 4 sites on the public website. If they are all listed as not recruiting, then I don't have any update.

Thanks,
Kanwen

From: Brodie Barnard <Brodie.Barnard@claritidox.com>
Sent: Monday, June 19, 2023 10:14 AM
To: Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>; Yang, Kanwen <kyang@ptcbio.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>
Subject: [EXTERNAL] RE: PTC596-ONC-007-LMS monthly update | Update

Thanks Dennis!

Nice to meet you [@Yang, Kanwen](#). We look forward to working with you. It's time to update the protocol posting on CTRM with any changes since the last release. Do you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Below is the link of CT.gov for you to refer what is there on the public site currently:

<https://clinicaltrials.gov/ct2/show/NCT03761095?term=PTC596-ONC-007&draw=2&rank=1>



[A Study of Unesbulin \(PTC596\) in Combination With Dacarbazine in Participants With Advanced Leiomyosarcoma \(LMS\) - Full Text View - ClinicalTrials.gov](#)

A Study of Unesbulin (PTC596) in Combination With Dacarbazine in Participants With Advanced Leiomyosarcoma (LMS) - Full Text View.

clinicaltrials.gov

Even if there are no updates, we will still route a form through CTRM for approval so that the validation date in the system stays current.

Kind regards,
Brodie

From: Nazareno, Dennis <jnazareno@ptcbio.com>
Sent: Monday, June 19, 2023 10:04 AM
To: Brodie Barnard <Brodie.Barnard@claritidox.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>; Yang, Kanwen <kyang@ptcbio.com>
Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Hi Brodie,
Her email is kyang@ptcbio.com and copied her here as well.

Best regards,
Dennis

Dennis Nazareno

Exec. Director, Clinical Process Optimization

Office: 1.908.912.9360

Mobile: 1.732.570.2668

Email: jnazareno@ptcbio.com

PTC Therapeutics

100 Corporate Court
South Plainfield, NJ 07080

www.ptcbio.com

From: Brodie Barnard <Brodie.Barnard@claritidox.com>
Sent: Monday, June 19, 2023 9:58 AM
To: Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>
Subject: RE: PTC596-ONC-007-LMS monthly update | Update

Thanks Dennis,

Can you send Kanwen's email address? This study is overdue for an update. We will reach out asap.

Best regards,
Brodie

From: Nazareno, Dennis <jnazareno@ptcbio.com>

Sent: Monday, June 19, 2023 9:12 AM

To: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Cc: Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>

Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Hi Abhijeet,

Kanwen Yang has transitioned to this study and will be the CTM to review registration for updates. I will schedule a training for her and Mark.

Best regards,
Dennis

Dennis Nazareno

Exec. Director, Clinical Process Optimization

Office: 1.908.912.9360

Mobile: 1.732.570.2668

Email: jnazareno@ptcbio.com

PTC Therapeutics

100 Corporate Court

South Plainfield, NJ 07080

www.ptcbio.com

From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Sent: Tuesday, June 13, 2023 3:27 PM

To: Nazareno, Dennis <jnazareno@ptcbio.com>

Cc: Brodie Barnard <brodie.barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; Rance, Mark <mrance@ptcbio.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Dennis,

Just wanted to follow up with you on the below email. Do you have information about the study team for this study?

Thanks!

Warm Regards,

Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Sent: Friday, May 26, 2023 4:49 PM

To: Nazareno, Dennis <jnazareno@ptcbio.com>

Cc: Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; mrance@ptcbio.com <mrance@ptcbio.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Dennis,

I just realized that Silvie is also no longer with PTC. Please let me know her delegate once you have information.

Thanks!

Warm Regards,
Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Sent: Friday, May 26, 2023 4:29 PM

To: Aarts, Silvie <saarts@ptcbio.com>

Cc: Nazareno, Dennis <jnazareno@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; mrance@ptcbio.com <mrance@ptcbio.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Silvie,

Just wanted to follow up with you on the below email. Could you please let us know if you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Thanks!

Warm Regards,
Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Sent: Thursday, May 18, 2023 5:02 PM

To: Aarts, Silvie <saarts@ptcbio.com>

Cc: Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Silvie,

Since Joan is OOO, could you please let us know if you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Thanks!

Warm Regards,

Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Sent: Thursday, May 18, 2023 4:54 PM

To: Caicco, Joan <jcaicco@ptcbio.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,

It's time to update the protocol posting on CTRM with any changes since the last release. Do you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Below is the link of CT.gov for you to refer what is there on the public site currently:

<https://clinicaltrials.gov/ct2/show/NCT03761095?term=PTC596-ONC-007&draw=2&rank=1>

	<p>A Study of Unesbulin (PTC596) in Combination With Dacarbazine in Participants With Advanced Leiomyosarcoma (LMS) - Full Text View - ClinicalTrials.gov</p>
	<p>A Study of Unesbulin (PTC596) in Combination With Dacarbazine in Participants With Advanced Leiomyosarcoma (LMS) - Full Text View.</p>
	<p>clinicaltrials.gov</p>

Even if there are no updates, we will still route a form through CTRM for approval so that the validation date in the system stays current.

Thanks!

Warm Regards,

Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Caicco, Joan <jcaicco@ptcbio.com>

Sent: Tuesday, April 18, 2023 10:01 PM

To: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>
Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Hi Abhijeet,

Done!

Kind regards,
 Joanie

Joanie Caicco
 Senior Manager, Clinical Operations
Mobile: 1.732.943.8723
Email: jcaicco@ptcbio.com
 100 Corporate Court
 South Plainfield, NJ 07080

www.ptcbio.com

Upcoming OOO:
 May 15-22, 2023

From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Sent: Monday, April 17, 2023 11:37 AM
To: Caicco, Joan <jcaicco@ptcbio.com>
Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>
Subject: [EXTERNAL] Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,
 Kindly consider this as a gentle reminder for your pending review task of this record. Below is the link for your quick access:

View the form [Protocol Registration Form](#).

When you are finished, please mark your [task](#) complete.

Thanks!
 Warm Regards,
 Abhijeet Srivastava
ClaritiDox LLC
 Email: Abhijeet.Srivastava@ClaritiDox.com



From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Sent: Tuesday, April 11, 2023 2:32 PM
To: Caicco, Joan <jcaicco@ptcbio.com>
Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>
Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,
 Thanks for the confirmation. Even if there are no updates, I still routed the form through CTRM for approval so that the validation date in the system stays current.
 The task is now assigned to you in CTRM. Please mark the task complete.

View the form [Protocol Registration Form](#).

When you are finished, please mark your [task](#) complete.

Thanks!
 Warm Regards,
 Abhijeet Srivastava
ClaritiDox LLC
 Email: Abhijeet.Srivastava@ClaritiDox.com



From: Caicco, Joan <jcaicco@ptcbio.com>
Sent: Monday, April 10, 2023 6:15 PM
To: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>
Subject: PTC596-ONC-007-LMS monthly update | Update

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Hi Abhijeet,

Thank you for the reminder. I confirm that there are no updates for this month.

Kind regards,
 Joanie

Joanie Caicco
 Senior Manager, Clinical Operations
Mobile: 1.732.943.8723
Email: jcaicco@ptcbio.com

Upcoming OOO:
 April 17, 2023
 May 15-22, 2023

100 Corporate Court
 South Plainfield, NJ 07080

www.ptcbio.com

From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Sent: Monday, April 10, 2023 3:56 AM
To: Caicco, Joan <jcaicco@ptcbio.com>
Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>
Subject: [EXTERNAL] Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,

Kindly consider this as a gentle reminder for your awaited response on the below email. Do you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Thanks!

Warm Regards,
Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Sent: Thursday, April 6, 2023 4:25 PM
To: jcaicco@ptcbio.com <jcaicco@ptcbio.com>
Cc: saarts@ptcbio.com <saarts@ptcbio.com>; jnazareno@ptcbio.com <jnazareno@ptcbio.com>; pmaliakal@ptcbio.com <pmaliakal@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Kimberly Green <Kim.Green@claritidox.com>
Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,

It's time to update the protocol posting on CTRM with any changes since the last release. Do you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Even if there are no updates, we will still route a form through CTRM for approval so that the validation date in the system stays current.

Thanks!

Warm Regards,
Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Brodie Barnard <Brodie.Barnard@claritidox.com>
Sent: Tuesday, March 14, 2023 12:35 AM
To: Maliakal, Pius <pmaliakal@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Srivastava, Abhijeet

<Abhijeet.Srivastava@informa.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: RE: PTC596-ONC-007-LMS monthly update | Update

Thanks Pius,

This update has been submitted to CT.gov.

Kind regards,
Brodie

From: Maliakal, Pius <pmaliakal@ptcbio.com>

Sent: Monday, March 13, 2023 10:57 AM

To: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Kimberly Green <Kim.Green@claritidox.com>; Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Thanks Abhijeet. Task Is completed.

Kind regards,

Pius

From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>

Sent: Monday, March 13, 2023 5:08 AM

To: Maliakal, Pius <pmaliakal@ptcbio.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Kimberly Green <Kim.Green@claritidox.com>; Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: [EXTERNAL] Re: PTC596-ONC-007-LMS monthly update | Update

Hi Pius,

The approval task is now assigned to you. Below is the link for your quick access:

View the submission [Submission](#) .

When you are finished, please mark your [task](#) complete.

Thanks!

Warm Regards,
Abhijeet Srivastava

ClaritiDox LLC

Email: Abhijeet.Srivastava@ClaritiDox.com



From: Caicco, Joan <jcaicco@ptcbio.com>

Sent: Friday, March 10, 2023 5:40 PM

To: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Kimberly Green <Kim.Green@claritidox.com>; Maliakal, Pius

<pmaliakal@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Good morning, Abhijeet,

Thank you for the reminder. Done!

Have a nice weekend.

Kind regards,

Joanie

Joanie Caicco
Senior Manager, Clinical Operations
Mobile: 1.732.943.8723
Email: jcaicco@ptcbio.com

Upcoming Business Travel:
27Mar-31Mar2023

100 Corporate Court
South Plainfield, NJ 07080

Upcoming OOO:
03-04Apr2023

www.ptcbio.com

From: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>

Sent: Wednesday, March 1, 2023 1:33 PM

To: Caicco, Joan <jcaicco@ptcbio.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Kimberly Green <Kim.Green@claritidox.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Abhijeet Srivastava <abhijeet.srivastava@claritidox.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,

Thanks for the confirmation. Even if there are no updates, I still routed the form through CTRM for approval so that the validation date in the system stays current.

The task is now assigned to you in CTRM. Please mark the task complete.

View the form [Protocol Registration Form](#).

When you are finished, please mark your [task](#) complete.

Thanks!

Warm Regards,

Abhijeet

From: Caicco, Joan <jcaicco@ptcbio.com>

Sent: Wednesday, March 1, 2023 4:20 PM

To: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Kimberly Green <Kim.Green@claritidox.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Abhijeet Srivastava <abhijeet.srivastava@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: RE: PTC596-ONC-007-LMS monthly update | Update

Hi Abhijeet,

To confirm there are no updates to post at this time.

Thank you.

Kind regards,
Joanie

Joanie Caicco

Senior Manager, Clinical Operations

Mobile: 1.732.943.8723

Email: jcaicco@ptcbio.com

100 Corporate Court
South Plainfield, NJ 07080

www.ptcbio.com

From: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>

Sent: Wednesday, March 1, 2023 4:43 AM

To: Caicco, Joan <jcaicco@ptcbio.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Kimberly Green <Kim.Green@claritidox.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; Abhijeet Srivastava <abhijeet.srivastava@claritidox.com>

Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Joan,

It's time to update the protocol posting on CTRM with any changes since the last release. Do you have any updates (location, contact, recruiting status) or amendments for this study that should be incorporated?

Even if there are no updates, we will still route a form through CTRM for approval so that the validation date in the system stays current.

Thanks!
Warm Regards,
Abhijeet

From: Brodie Barnard <Brodie.Barnard@claritidox.com>

Sent: Monday, February 6, 2023 9:41 PM

To: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>; Maliakal, Pius <pmaliakal@ptcbio.com>; jbaj@ptcbio.com <jbaj@ptcbio.com>

Cc: Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Kimberly Green <Kim.Green@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>

Subject: RE: PTC596-ONC-007-LMS monthly update | Update

Hi Jane,

I hope you had a nice weekend. Are you able to please complete your approval task in Disclose? Thanks for your help.

Best regards,
Brodie

From: Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Sent: Thursday, January 26, 2023 2:21 PM
To: Maliakal, Pius <pmaliakal@ptcbio.com>; jbaj@ptcbio.com
Cc: Brodie Barnard <Brodie.Barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Srivastava, Abhijeet <abhijeet.srivastava@informa.com>; Kimberly Green <Kim.Green@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>
Subject: Re: PTC596-ONC-007-LMS monthly update | Update

Hi Jane and Pius,
The approval task is now assigned to you. Please review and mark your task complete.

Thanks!
Warm Regards,
Abhijeet Srivastava
ClaritiDox LLC
Email: Abhijeet.Srivastava@ClaritiDox.com



From: Caicco, Joan <jcaicco@ptcbio.com>
Sent: Thursday, January 26, 2023 12:51 AM
To: Kimberly Green <Kim.Green@claritidox.com>; Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Maliakal, Pius <pmaliakal@ptcbio.com>
Cc: Brodie Barnard <Brodie.Barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>
Subject: RE: PTC596-ONC-007-LMS monthly update | Update

You don't often get email from jcaicco@ptcbio.com. [Learn why this is important](#)

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Got it. I just went in and completed tasked. Confirmed in comments. I should be done.

Regards,
Joanie

From: Kimberly Green <Kim.Green@claritidox.com>
Sent: Wednesday, January 25, 2023 2:18 PM
To: Caicco, Joan <jcaicco@ptcbio.com>; Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Maliakal, Pius <pmaliakal@ptcbio.com>
Cc: Brodie Barnard <brodie.barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Subject: [EXTERNAL] RE: PTC596-ONC-007-LMS monthly update | Update

Joan,
We had you and Pius review the study status change and anticipated study completion dates of 28-Feb, but then we held everything without releasing it. You'll see the notes in the form from that effort.
Warm regards,
Kim

From: Caicco, Joan <jcaicco@ptcbio.com>
Sent: Wednesday, January 25, 2023 2:11 PM
To: Kimberly Green <Kim.Green@claritidox.com>; Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Maliakal, Pius <pmaliakal@ptcbio.com>
Cc: Brodie Barnard <Brodie.Barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>
Subject: RE: PTC596-ONC-007-LMS monthly update | Update

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Thank you, Kimberly. I do not recall the study status change was already in the workflow!.

I will go in now and I gave a head's up to Pius re: your override to "check-in"

Regards,
Joanie

From: Kimberly Green <Kim.Green@claritidox.com>
Sent: Wednesday, January 25, 2023 2:04 PM
To: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Caicco, Joan <jcaicco@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>
Cc: Brodie Barnard <brodie.barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Subject: [EXTERNAL] RE: PTC596-ONC-007-LMS monthly update | Update

Hi Team,

I went ahead and did an over-ride check in on the form in Disclose, assuming Pius did not realize he had the study checked out. I also implemented the anticipated study completion dates per Joan's email below (the study's overall status was previously updated to Active, Not Recruiting but had not yet been released to CTgov with that status; it still says Recruiting on CTgov). Since Abhijeet is already offline for the day, I also routed the form to Joan for review so we can get this workflow started, and I inserted new comments in the form where changes were made since Joan's last review.

Once Joan's review is marked complete, the submission form will be need to be approved by Lee, Jane, and Pius before it can be released. Dennis has already confirmed the investor relations is aware of these changes.

I will let Abhijeet and Brodie take things from here.

Warm regards,
Kim

From: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>
Sent: Wednesday, January 25, 2023 4:56 AM
To: Caicco, Joan <jcaicco@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Brodie Barnard <Brodie.Barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Nazareno, Dennis <jnazareno@ptcbio.com>; Abhijeet Srivastava <Abhijeet.Srivastava@claritidox.com>
Subject: Re: PTC596-ONC-007-LMS monthly update | Update
Importance: High

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Hi Joan,
Thanks for the update.

[@Maliakal, Pius](#), Could you please check in the 'Study properties' in the Disclose system? Once you check-in the 'Study properties', I will make the updates and send it for review/approval.

Thanks!
Warm Regards,
Abhijeet

From: Caicco, Joan <jcaicco@ptcbio.com>
Sent: Wednesday, January 25, 2023 1:29 AM
To: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>; Nazareno, Dennis <jnazareno@ptcbio.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Aarts, Silvie <saarts@ptcbio.com>; Caicco, Joan <jcaicco@ptcbio.com>; Maliakal, Pius <pmaliakal@ptcbio.com>
Subject: PTC596-ONC-007-LMS monthly update | Update

Dear Abhijeet,

Our team has received internal approval to move forward with the following updated information in CT.gov for study PTC596-ONC-007-LMS. Abhijeet, please update as follows and route for approvals:

- Estimated Primary Completion Date: **July 31, 2023**
- Estimated Study Completion Date: **July 31, 2023**
- Recruitment Status: **Active, not recruiting.**

Thank you in advance for your prompt attention to this request.

Kind regards,
Joanie

Joanie Caicco
Senior Manager, Clinical Operations
Mobile: 1.732.943.8723
Email: jcaicco@ptcbio.com

100 Corporate Court
South Plainfield, NJ 07080

www.ptcbio.com

From: Nazareno, Dennis <jnazareno@ptcbio.com>
Sent: Wednesday, November 2, 2022 4:00 PM
To: Srivastava, Abhijeet <Abhijeet.Srivastava@informa.com>
Cc: Kimberly Green <Kim.Green@claritidox.com>; Brodie Barnard <brodie.barnard@claritidox.com>; Caicco, Joan <jcaicco@ptcbio.com>; Aarts, Silvie <saarts@ptcbio.com>
Subject: PTC596-ONC-007-LMS monthly update

Hi Abhijeet,
Given that we have not been able to release any updates for PTC596-ONC-007-LMS for the last couple of months we want to make sure that we are ready and prepared to post new updates upon moments notice. Therefore, could you kindly initiate the review workflow as per our regular process? Once the review is completed I will then give you the green light to release the updates.

Let me know if you have any questions. Thanks in advance.

Best regards,
Dennis

Dennis Nazareno

Exec. Director, Clinical Process Optimization

Office: 1.908.912.9360

Mobile: 1.732.570.2668

Email: jnazareno@ptcbio.com

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