

SBIA-DMF Drug substance workshop

March 3 & 4, 2021 (Virtual)

FDA

Teleconference

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Virtual

PURPOSE

To show the process and steps for Teleconference and its effectiveness.

Teleconference (*aka DMF Meeting Request*)

1. T-con is a highly effective formal communication path.
2. Highlight process steps and timelines for T-con for Agency and Industry.
3. Explain the Grant/Deny process for T-con.

OBJECTIVE(S)

1. T-con is a formal communication tool under GDUFA.
2. T-con is dedicated to 1st Cycle Complete Response Letters.
3. Review and response timelines of T-con request.
4. Agency's internal review process.
5. T-con is an avenue worth exploring by DMF holders.

METHOD(S)

This presentation has 4 Sections

1. What qualifies for Teleconference.
2. Response Timelines for Teleconference upon receipt.
3. Capturing the Grant/Deny process, and Email Exchange.
4. Resources available to the industry.

RESULT(S)

T-Con Vs. Email Exchange

Fiscal Year	FY17	FY18	FY19	FY20
Total # of meetings requested	20	12	6	3
Total # of meetings granted	18	11	6	3
Total number of meetings via written response	15	8	6	2
Total number of granted meetings that included a written response	14	28	21	10

Fiscal Year	FY18	FY19	FY20 Total
Total Initial Email Exchanges (EE) completed	60	65	80
Median days to response-Initial EE	12	16	9
Total Follow-up EE completed	10	2	16
Median days to response-Follow-up EE	10	12	8

CONCLUSION(S)

- For questions regarding CR01, encourage Industry to utilize T-con process.
- Follow the instructions on the CR letter to submit the T-con requests in a timely manner.
- Email Exchange is as effective as T-con and does not depend on the type of letter or the review cycle.

WHERE TO GET MORE INFORMATION

Send questions regarding this poster to: DMFOGD@FDA.HHS.GOV by 2/15/2021 for inclusion in the poster Q&A session on March 3rd.



Teleconference

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Teleconference

(aka DMF Meeting Request)



- Teleconference is:
 - **ONE** of two modes of formal communication available to Drug Master File (DMF) holders.
 - 1st implemented under **GDUFA I**.
 - Highly effective.
 - Popularly referred to as **DMF Meeting Request**.

Process steps for Industry

DMF Holders

- can request a **30-minute** Teleconference (T-con) to discuss content of the DMF First Cycle review deficiencies issued in a Completed Response Letter (CRL).
- must request such teleconferences in writing within **20 business days** of issuance of the CRL, identifying specific issues to be addressed.

The written request

- should be submitted through the Electronic Submissions Gateway (ESG).
- should send a notification e-mail to DMFOGD@fda.hhs.gov and carbon copy the Regulatory Business Process Manager (RBPM) listed on the CRL.

Agency Process

T-Con Received

Once the formal meeting request is received, it will be processed into the DMF records and a meeting project will be created.

Task Assignment

Office of Program and Regulatory Operations (OPRO) RBPM assigns the task to the Division of Lifecycle (DLAPI) review team.

Decision Step

DLAPI has 20 days to provide one of the following:

- ★ Grant T-con
- ★ Grant T-con with Written Response
- ★ Deny Meeting Request

Grant/Deny Decision

Grant T-Con:

- ★ A **30-minute** meeting is granted. The OPRO RBPM works with the firm to schedule the meeting.

Grant T-con

with Written response:

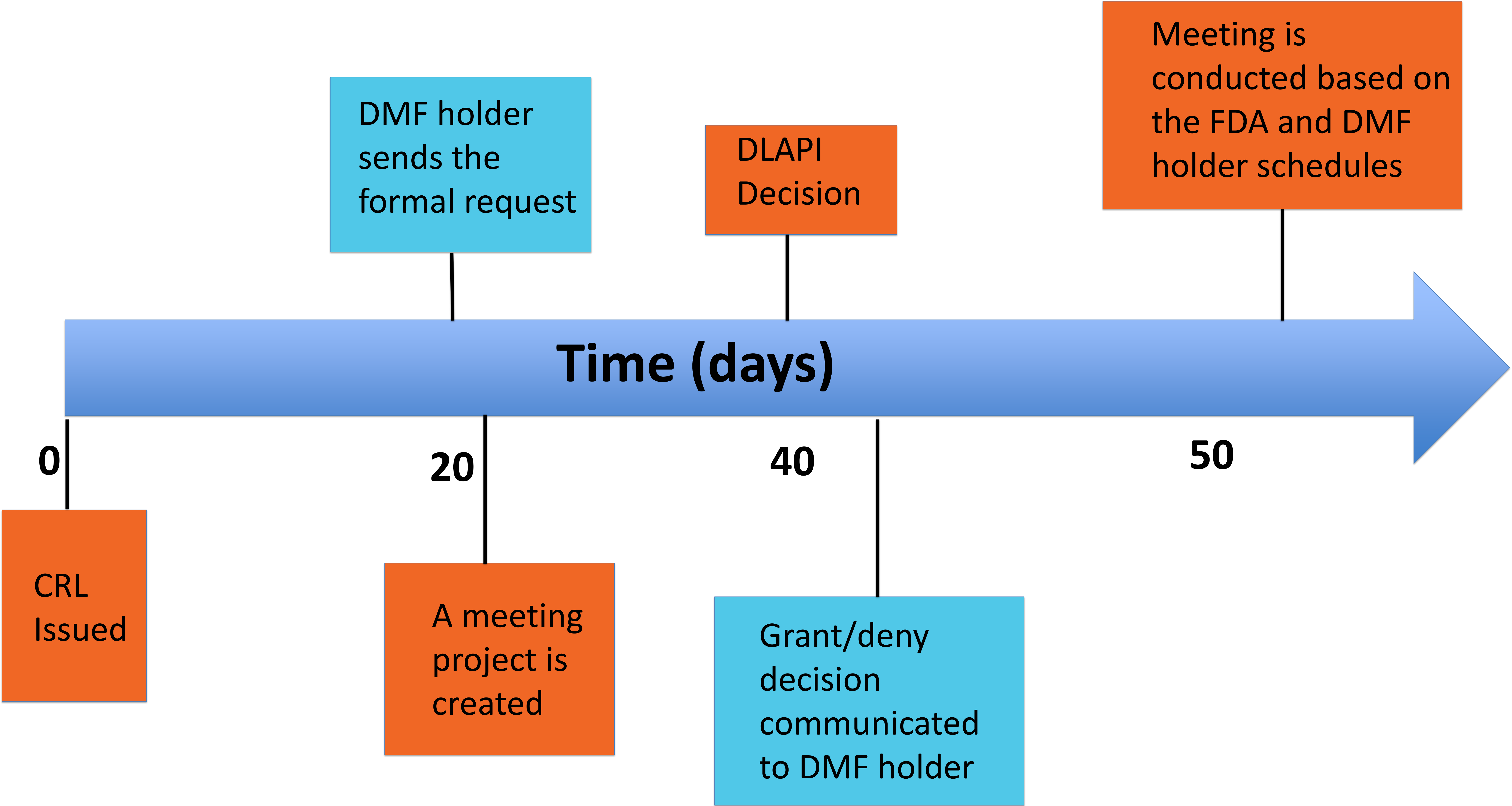
- ★ A **30-minute** meeting is granted with written response to the DMF holders queries. If the written responses suffice, then DMF holder may opt not to schedule a meeting. Otherwise, OPRO RBPM works with the firm to schedule a meeting

Deny Meeting

Request:

- ★ If the questions are not specific or not related to the content of the CRL, or not received in a timely way, the meeting request is
 - ★ denied
- In the case of denial due to a late request an Email Exchange will be offered.

T-con Timeline



Email Exchange in Lieu of T-cons



- Upon reviewing the DMF holders request, if a T-con cannot be processed, the holder will be notified via email to send the request as an Email Exchange.
- Email Exchanges are as effective as the T-con process.
- Email Exchanges are **not** specific to a letter type or a review cycle.
- Seem to be popular with the Industry.

Email Exchange in Lieu of T-cons

Deciding on which one to use:

- Teleconference:-
 - Limited to FIRST Cycle DMF CR letters only.
 - Written request required within 20 business days of CR letter receipt.
 - Must be in identification to specific issues in CR letter.
 - Up to 30 days of GRANT/DENY time frame.
- Email Exchange:-
 - Some flexibility on what qualifies.
 - Can be submitted for any review cycle or type of review letter (CR or DMF Deficiency letter).
 - Eligible for ONE follow up request after the initial email exchange response.
 - Response within 30 calendar days.



Data comparing extent of T-Cons and Email Exchanges

T-Con Meetings by FDA Fiscal Year **Email Exchange by FDA Fiscal Year**

Fiscal Year	FY17	FY18	FY19	FY20	Total	Fiscal Year	FY18	FY19	FY20	Total
Total number of meetings requested	20	12	6	3	41	Total Initial Email Exchanges (EE) completed	60	65	80	205
Total number of meetings granted	18	11	6	3	38	Total Follow-up EE completed	10	2	16	28

GDUFA II Commitment-T-con



Fiscal Year	FY17	FY18	FY19	FY20
Total number of meetings requested	20	12	6	3
Total number of meetings Granted	18	11	6	3
Median response time (in days) to grant meeting or grant with written response	14	28	21	10

GDUFA II Commitment-Email Exchange (EE)



Fiscal Year	FY18	FY19	FY20
Total Initial EE completed	60	65	80
Median days to response-Initial EE	12	16	9
Total Follow-up EE completed	10	2	16
Median days to response-Follow-up EE	10	12	8

Helpful Tips to Industry



- For questions regarding first cycle CRLs, we encourage you to utilize T-con process since these are direct meetings
- Follow the instructions on the CR letter to submit the T-con request in a timely manner
- Industry has found Email Exchange as an effective option and is available in situations where a T-con is not appropriate
- For questions, reach out to us at DMFOGD@fda.hhs.gov



Thank You!

- Send questions regarding this poster to: DMFWorkshop2021@fda.hhs.gov by 2/15/2021 for inclusion in the poster Q&A session on March 4th.
- Follow-on webinar for both posters/presentations on April 9, 2021. Questions can be sent to the above email by 3/19/2021 for the webinar.
- Please refer to the following presentation on March 3rd for additional information:

*“Effective Communication Strategies For Drug Master Files (DMF)” by
David Skanchy and Ben Danso*