U.S. FOOD & DRUG ADMINISTRATION

Introduction to the DMF Review Process

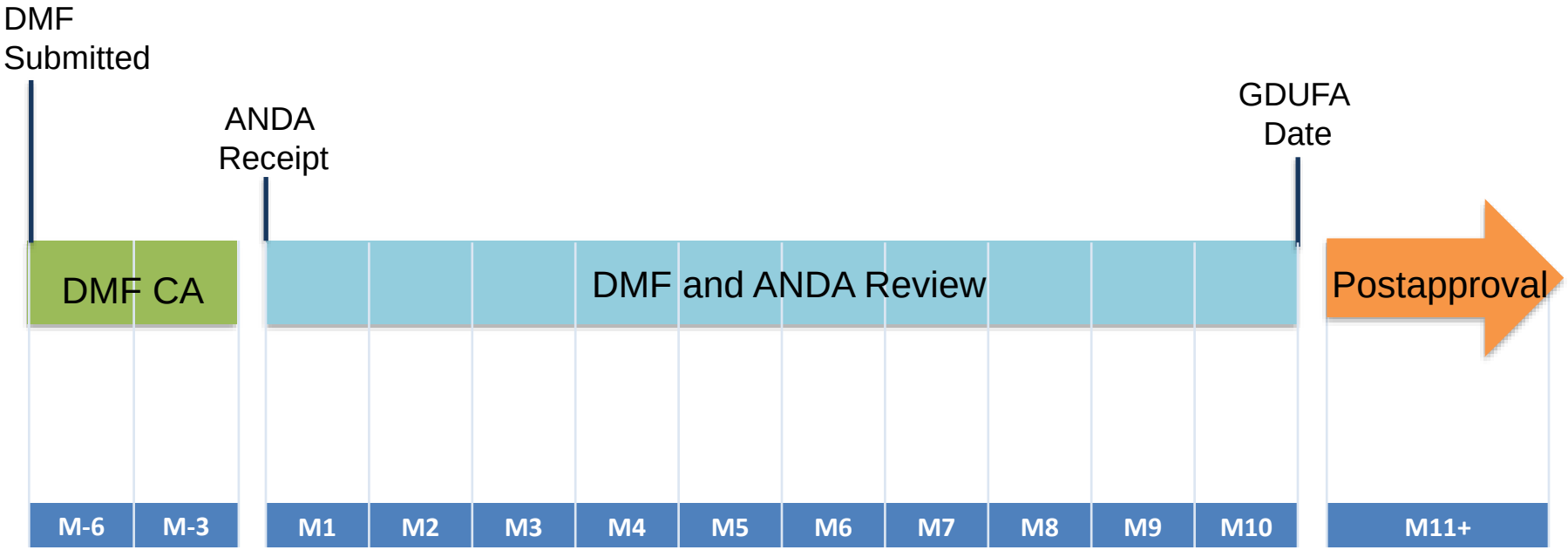
Erin Skoda, Ph.D.
Acting Branch Chief
Division of Lifecycle API, Office of New Drug Products
OPQ | CDER | US FDA

Drug Master File (DMF) and Drug Substance Workshop – March 3, 2021

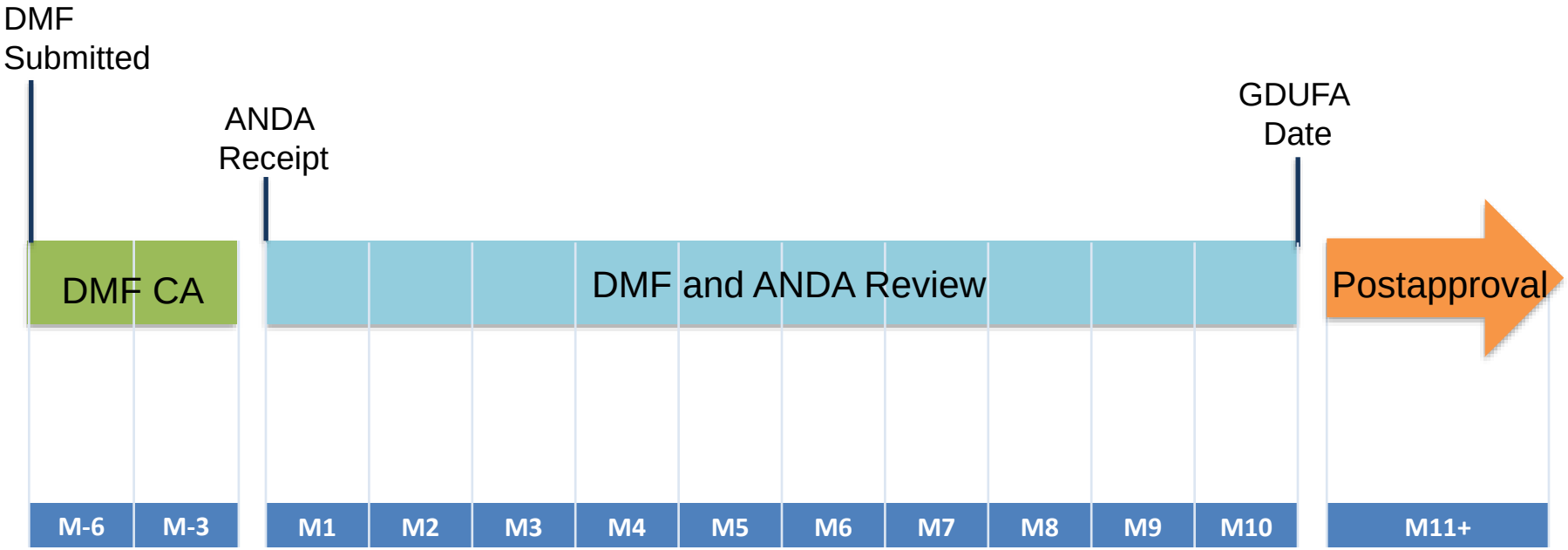
Objectives

- Gain a high-level understanding of the DMF review process from start to post-approval
- Describe how the DMF and ANDA review processes are related and dependent
- Learn how missteps during various stages can affect the review process

DMF Timeline Example



Pre-ANDA Receipt



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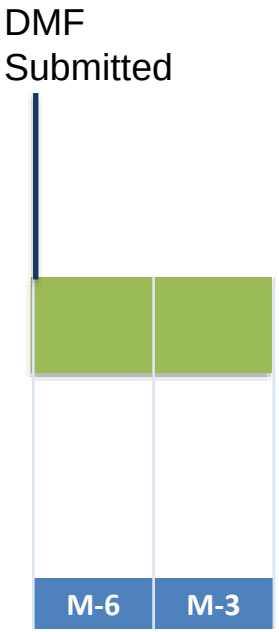
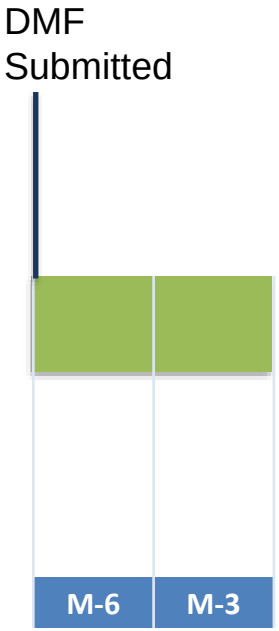


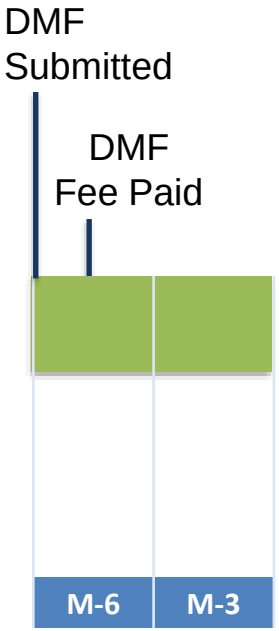
Submission of DMF



DMF Submissions:

- Successful submission necessary before CA can be complete
- Talk: *Managing Electronic DMF Submissions*

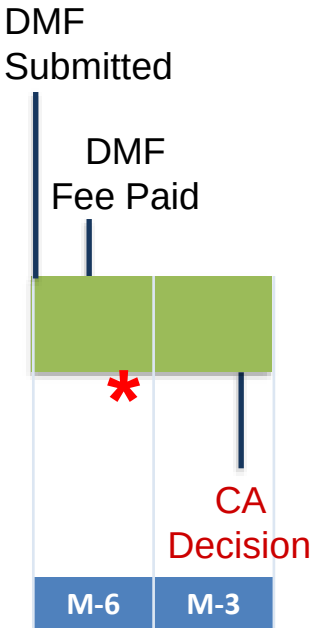
DMF Fee Payment



<u>DMF Fee</u>:

- Prerequisite to a CA
- Presentation: *Drug Master Files from a GDUFA User Fee Perspective*

Completeness Assessment

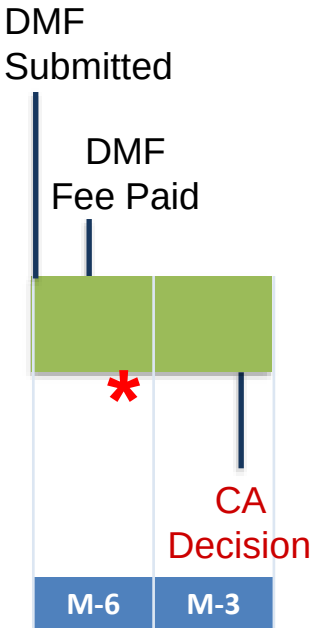


Completeness Assessment:

- Complete or Incomplete
- Available for reference list
- Administrative Maintenance
- Poster: *Completeness Assessments (CAs): Current CA Status, KASA for CA, Common Issues & GDUFA Commitment Letter Statistics*

*Suggested communication points between DMF and ANDA

After CA Decision

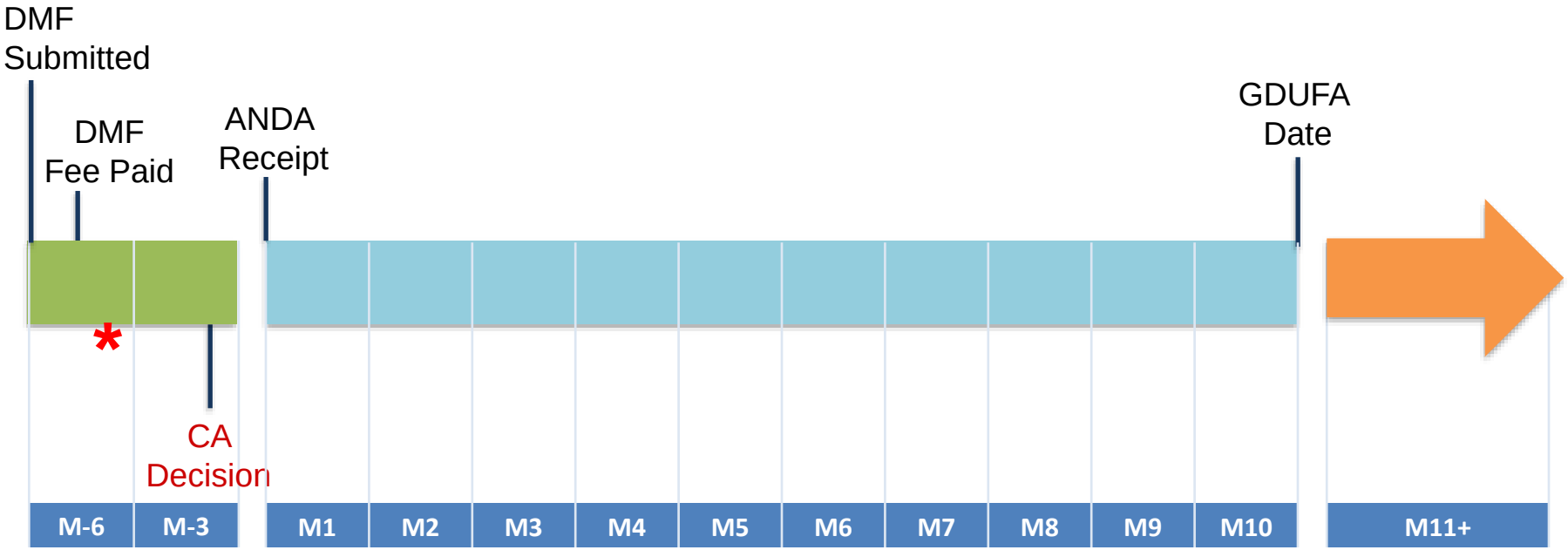


DMF Maintenance:

- Must continue regardless of your referenced status
- Presentation: Administrative Aspects of Managing a DMF

*Suggested communication points between DMF and ANDA

DMF Timeline



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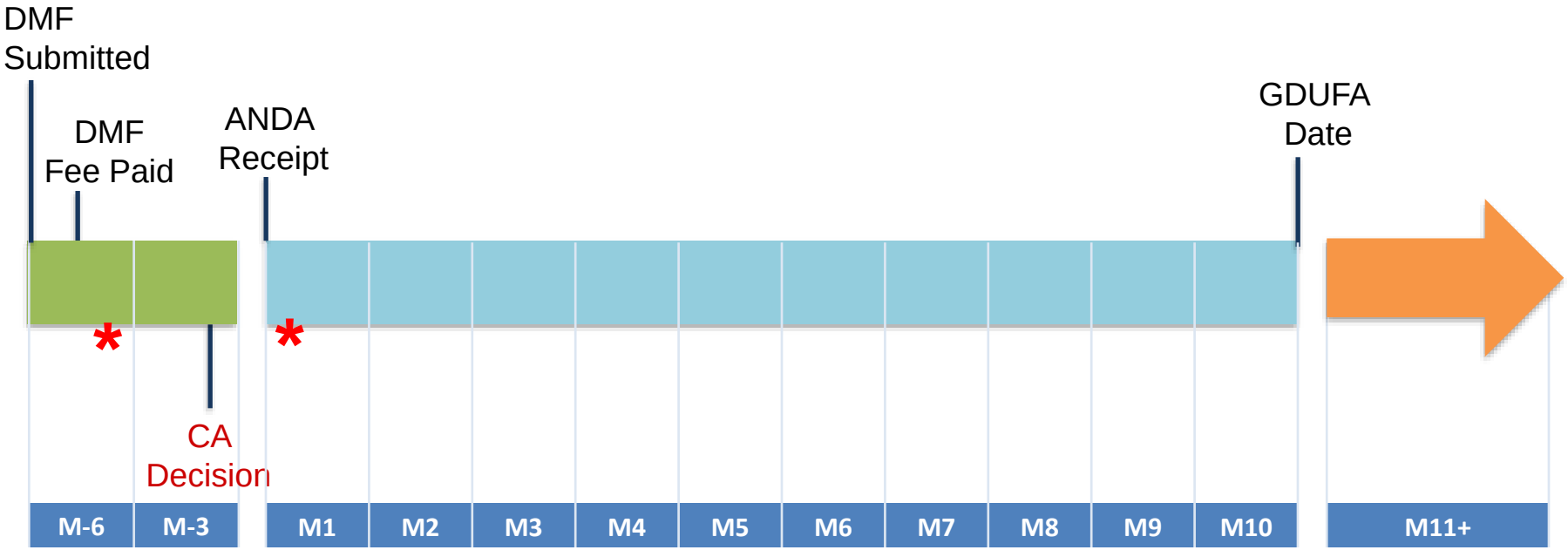
ANDA Receipt to GDUFA Date



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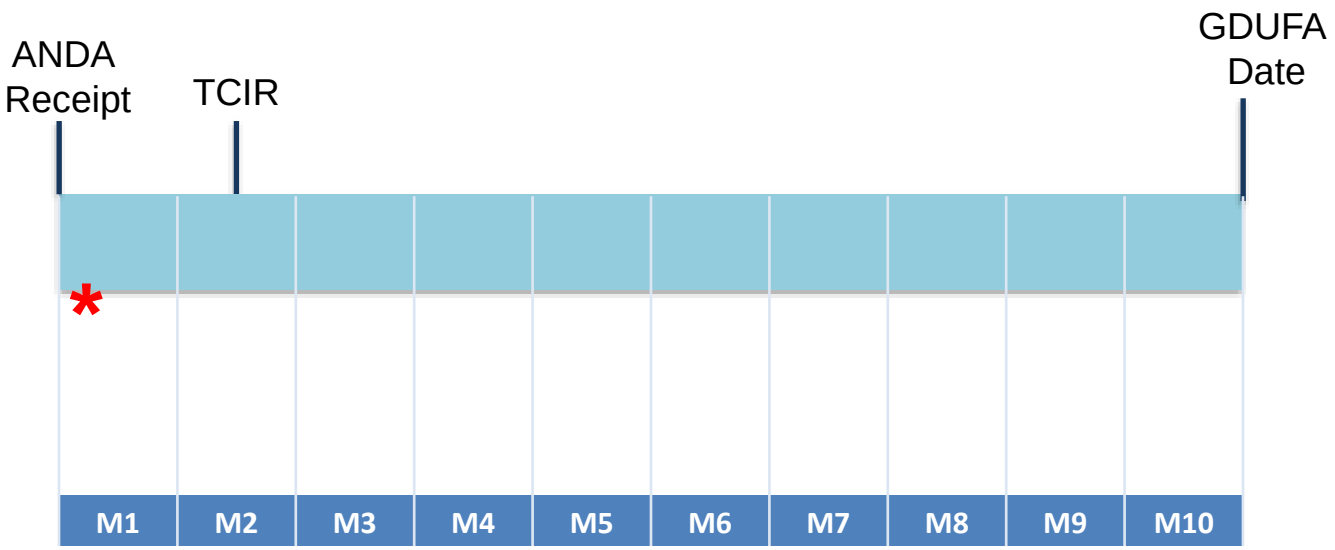
Timely Consults and Early IR (TCIR)



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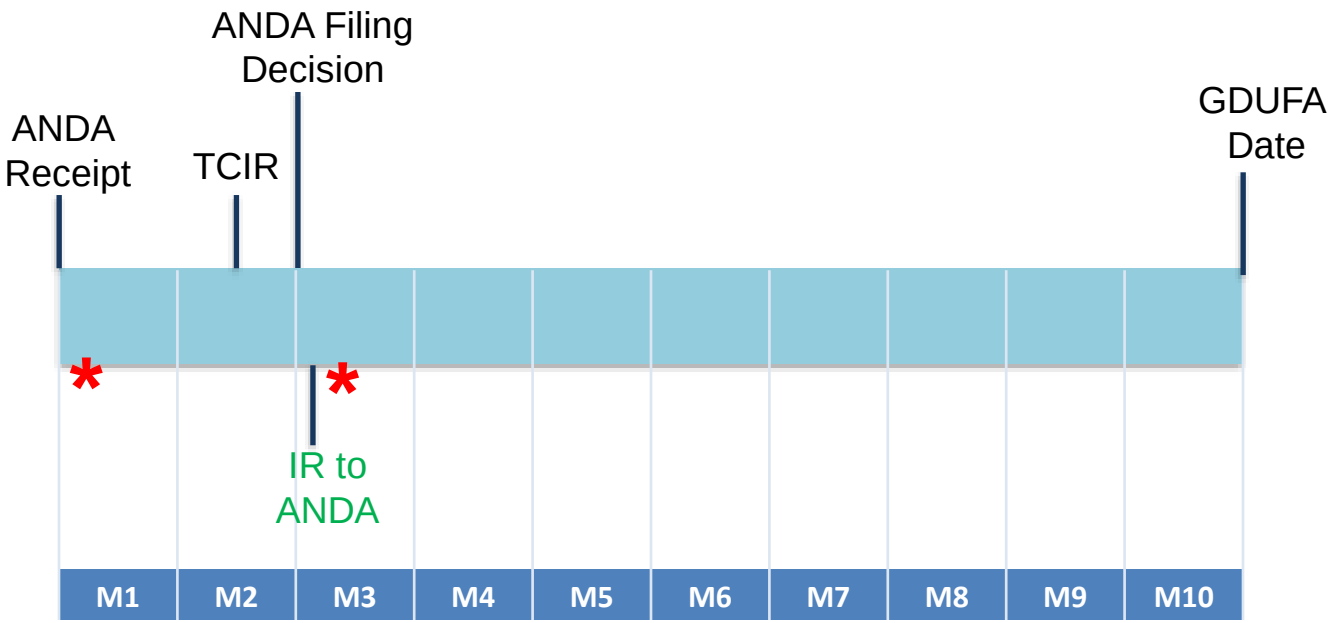

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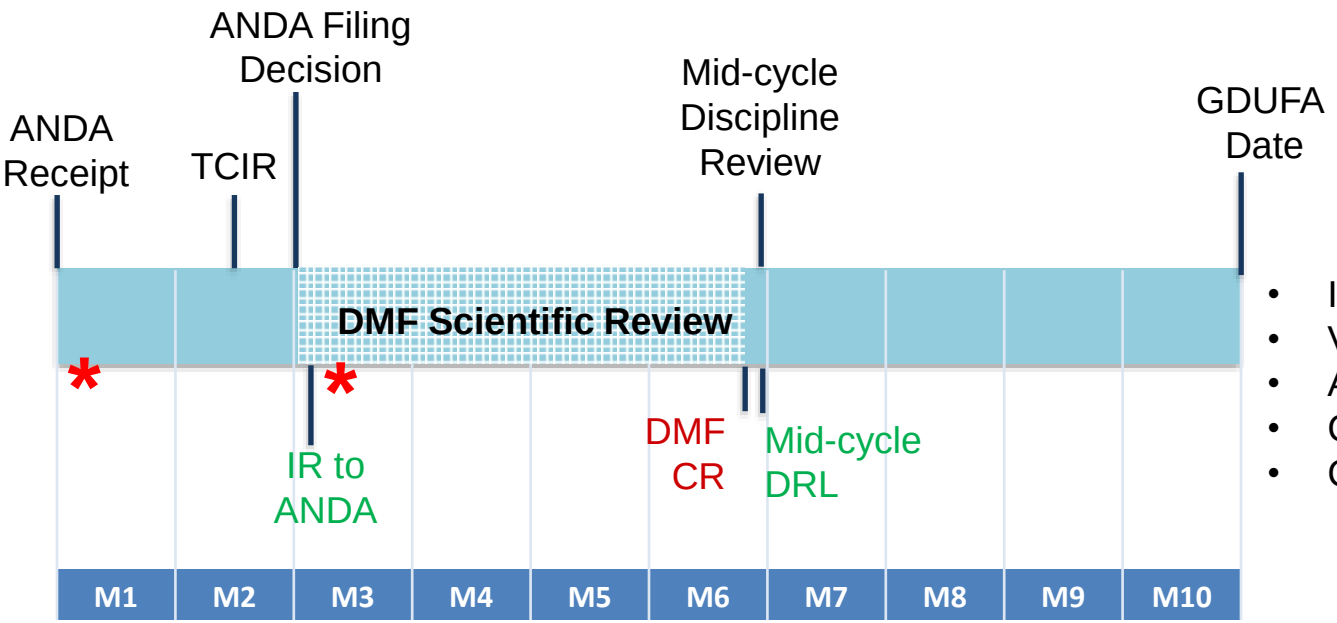
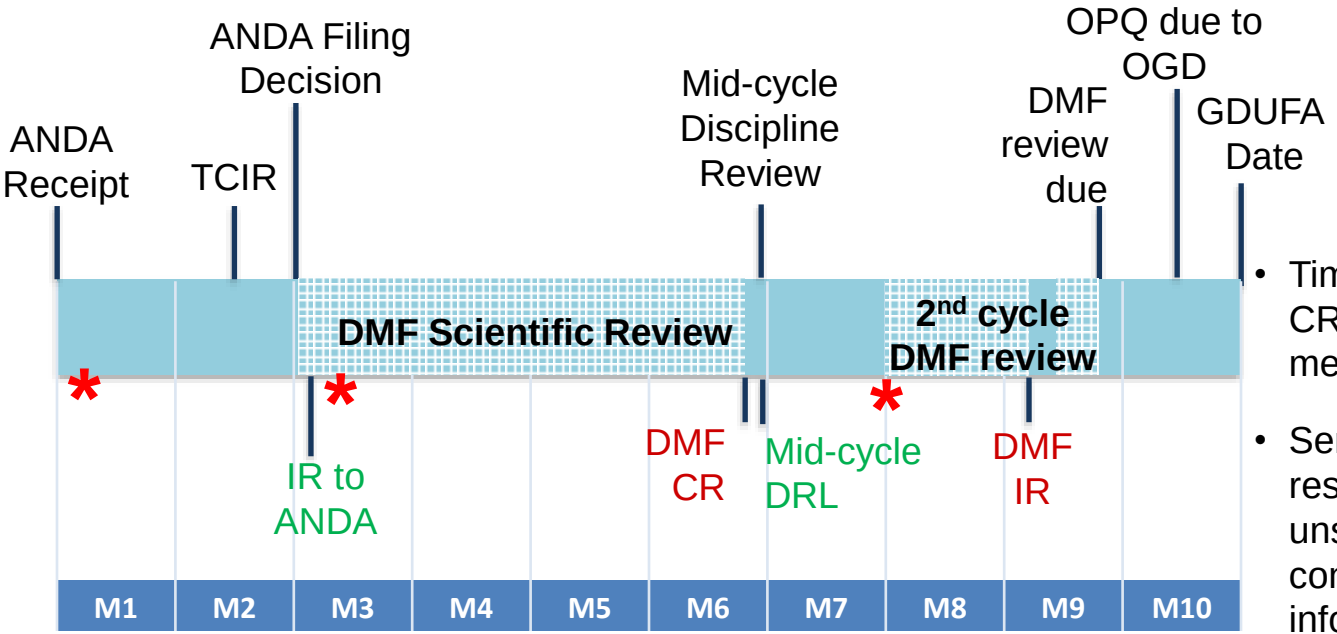
DMF Scientific Review



- Impurities
- Validation
- Analytical methods
- Complex APIs
- Common Issues

*Suggested communication points between DMF and ANDA

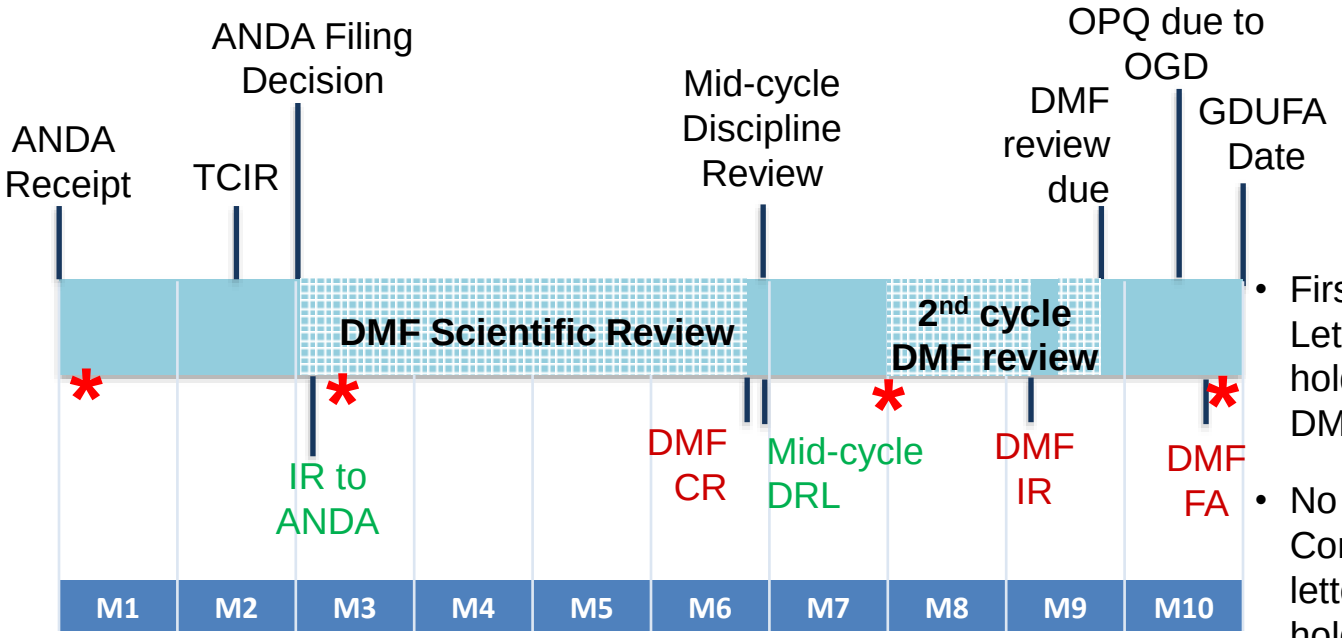
DMF Scientific Review



- Timely response to CR necessary for meeting GDUFA date.
- Sending in later responses or unsolicited consultable information could delay review.

*Suggested communication points between DMF and ANDA

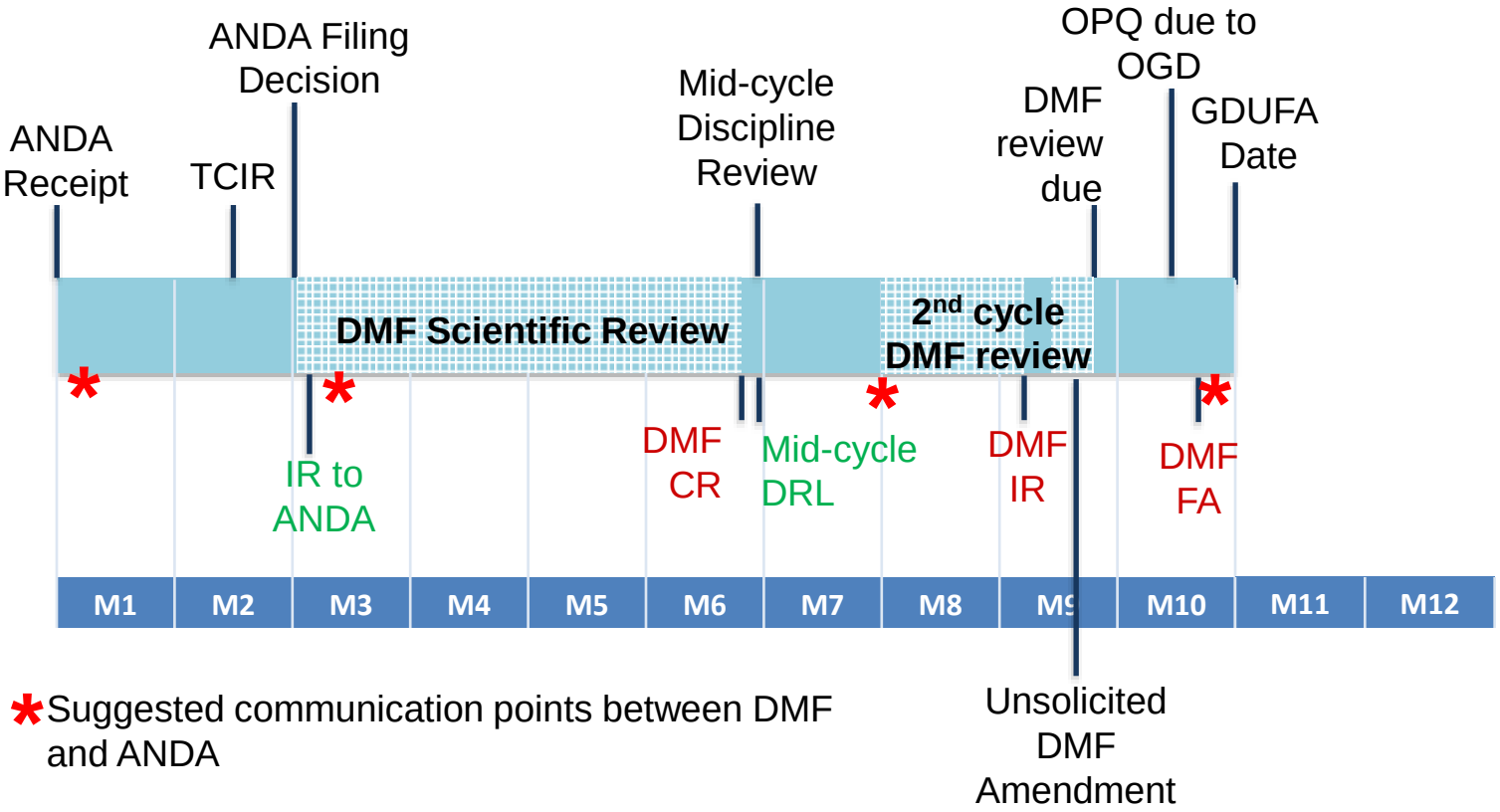
Communications following review



- First Adequate (FA) Letter sent to DMF holder 30 days after DMF review
- No Further Comments (NFC) letter sent to DMF holder 30 days after action

*Suggested communication points between DMF and ANDA

Communications



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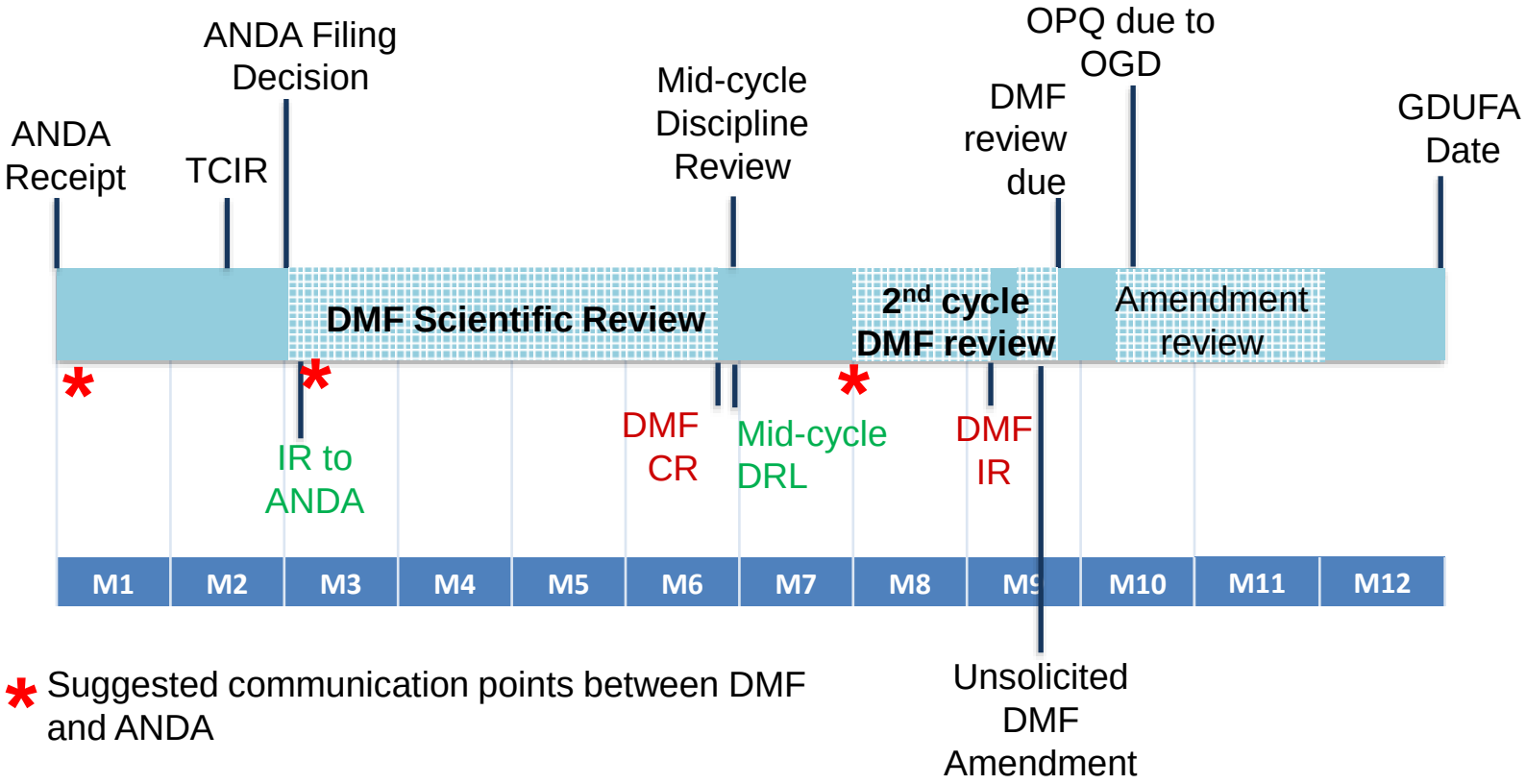

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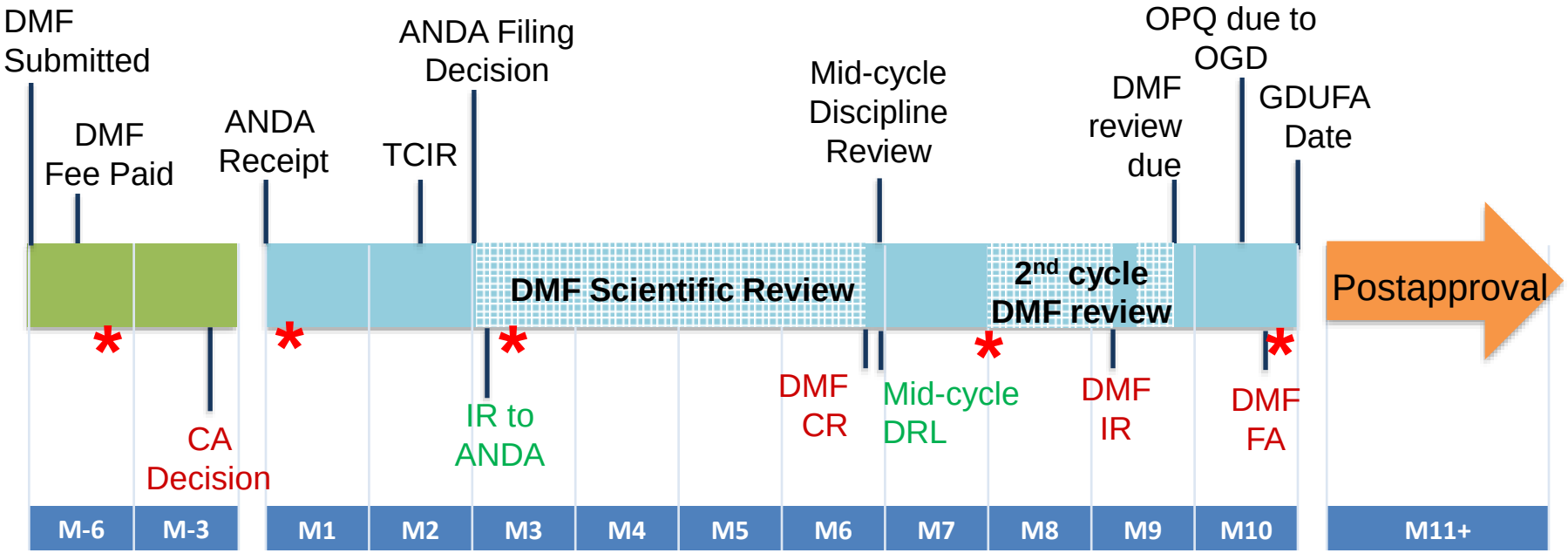
DMF Timeline

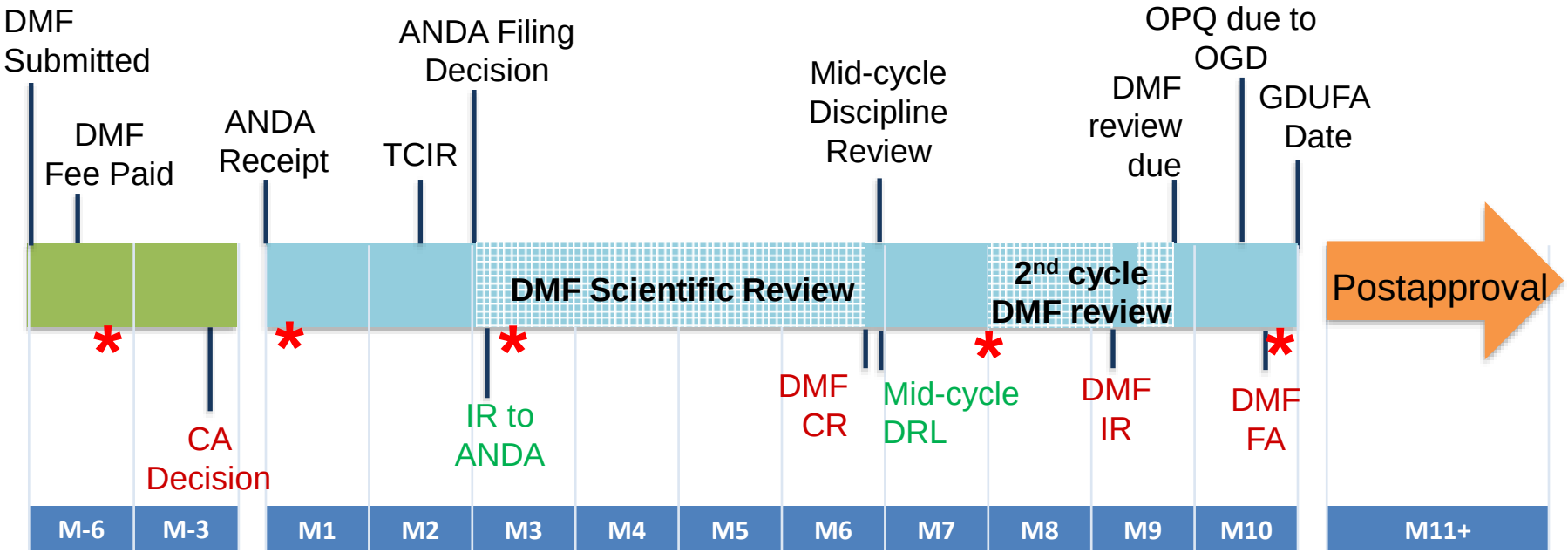


*Suggested communication points between DMF and ANDA

After ANDA approval

- No Further Comments Letter
- Administrative maintenance
- Up to date information on manufacturing and testing. See Post-Approval Changes for drug substance guidance.

DMF Timeline



*Suggested communication points between DMF and ANDA

Initiatives to facilitate efficiency

Summary

- Review process: DMF receipt through post-approval
- Communication is essential
- Agency efforts for improvement
- Additional resources

Thank you

- Thank you for your attendance

- Ee-Sunn (Joanne) Chia
- Dave Skanchy
- Wei Song

Questions?

- For questions regarding the content of this presentation, please type them into the "Q&A Box" so that they can be addressed during the panel Q&A after this session.

- To submit questions on this presentation for inclusion in the Follow-on webinar on April 9th , send them by March 19th to: DMFWorkshop2021@fda.hhs.gov

- Additional information on any of these topics can be found in either the poster presentations or full talks listed in our agenda

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