

GDUFA III Goal Date Illustrations

Learning Objectives

- When there will be extensions to goal dates
- When there will be no change to goal dates
- When there will be shortened goal dates
- When the Imminent Action process is used

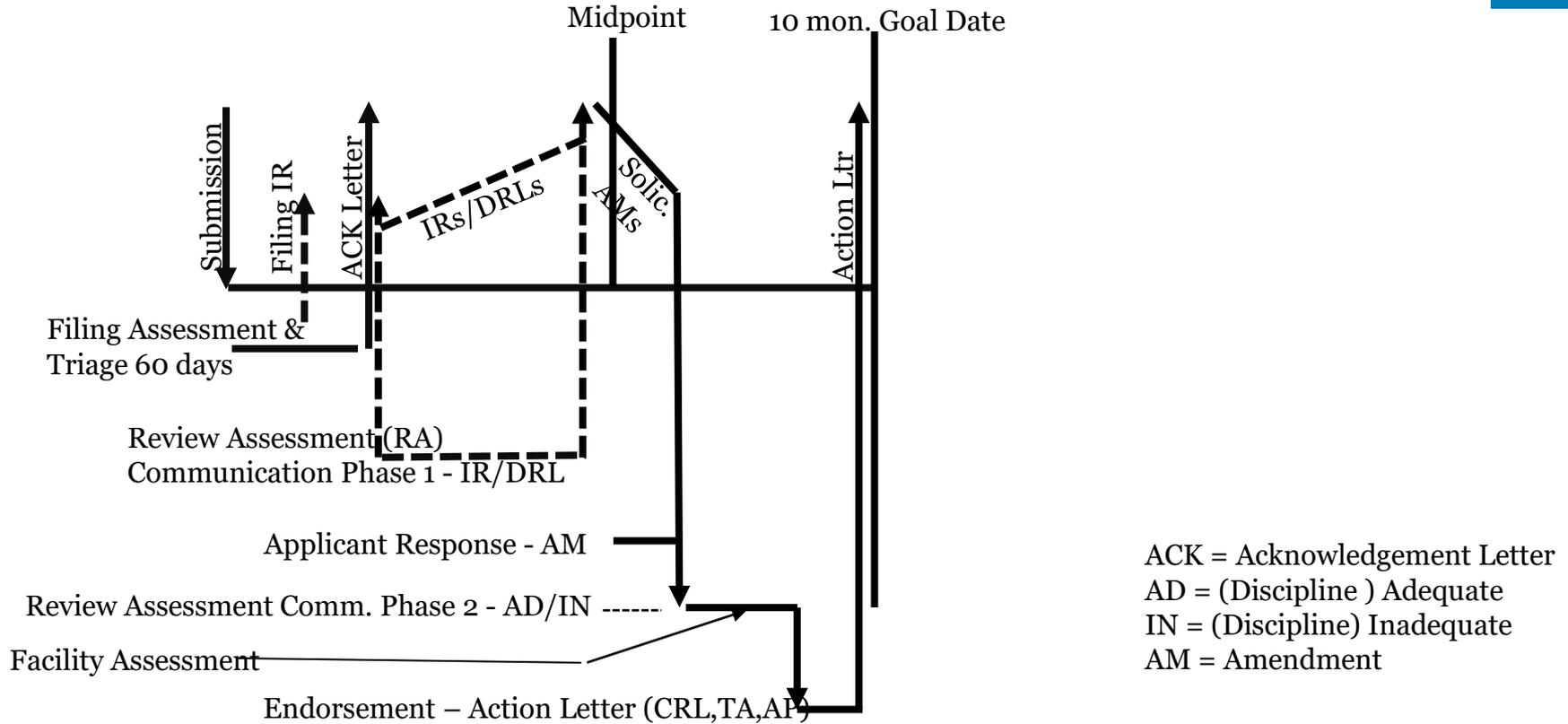
GDUFA III Goal Dates

- 1st Cycle Original ANDA from GDUFA II
- 1st Cycle Orig...GDUFA II w/**Pre-Submission Facility Correspondence**
- 1st Cycle Original w/Mid-cycle Minor Amendment (no extension)
- 1st Cycle Original w/Mid-cycle Major Amendment
- 1st Cycle Original w/Late-cycle IR/DRL
- 1st Cycle Original w/Mid-cycle Major Amend. w/Late-cycle IR/DRL

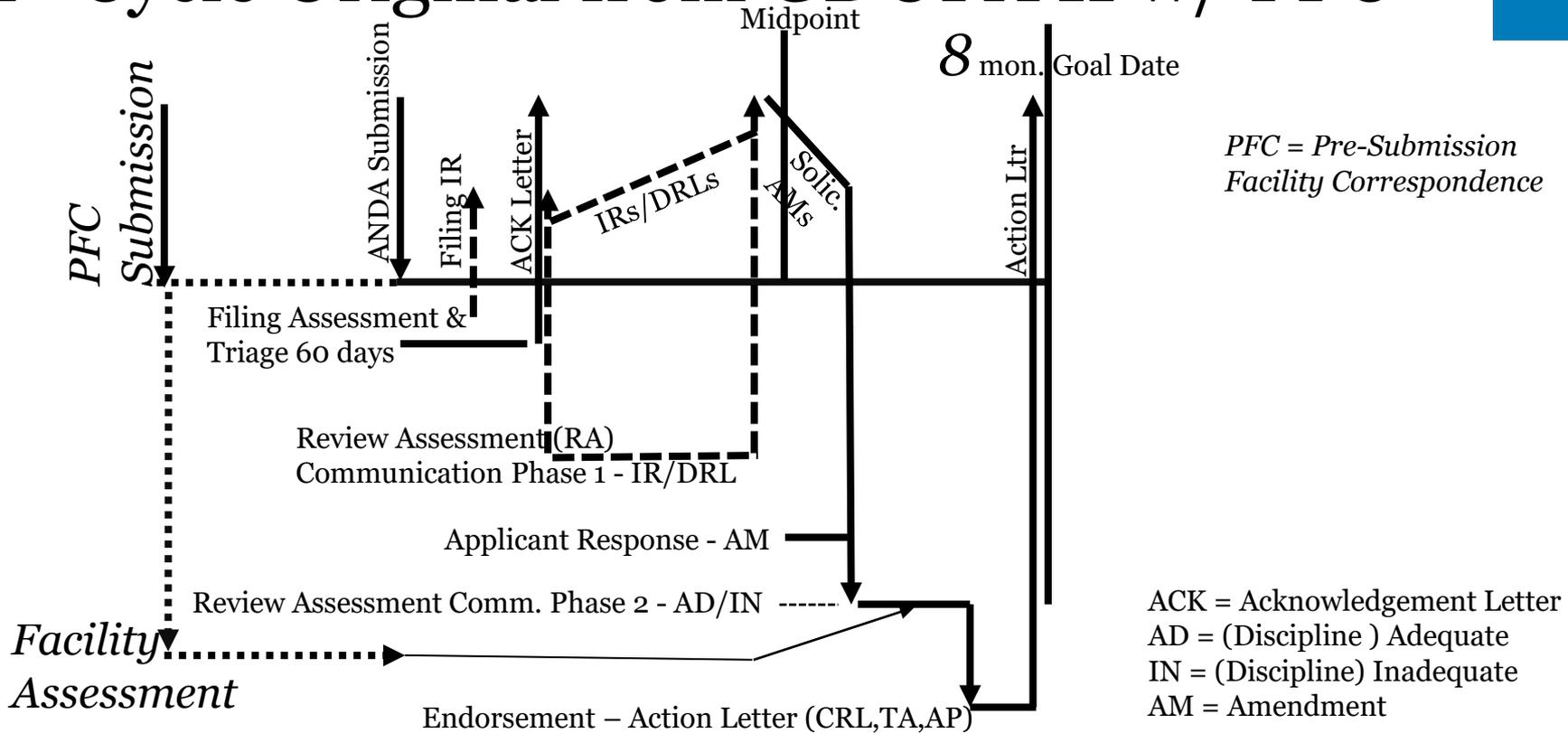
GDUFA III Goal Dates (cont.)

- 1st Cycle Original w/Mid-cycle Review Mtg. (MCRM) (no extension)
- 1st Cycle Original w/Enhanced MCRM (EMCRM)
- Subsequent Cycle Original w/ IR/DRL
- Facility Not Ready (at time of original submission)
- *Imminent Action (not an extension but meets goal)*

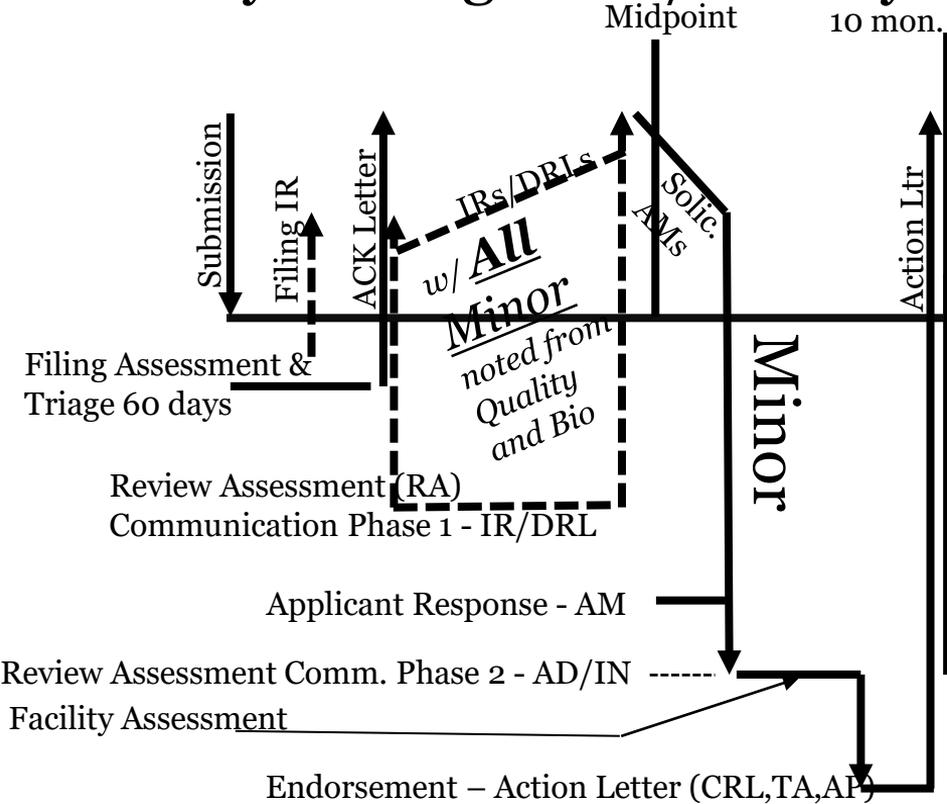
1st Cycle Original from GDUFA II



1st Cycle Original from GDUFA II w/ PFC



1st Cycle Original w/ Mid-cycle Minor Amendments



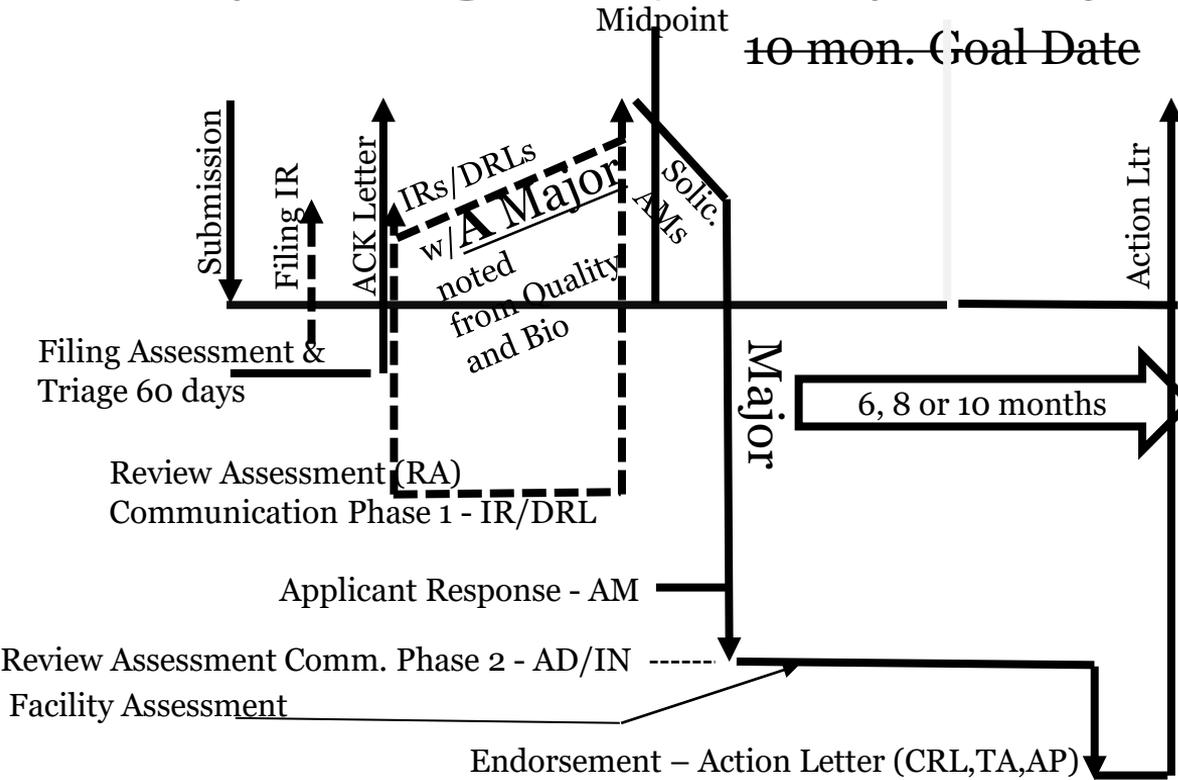
No change to goal date

Tips:

1. Respond on time
2. Thorough response
3. Alert discipline PM of issues

ACK = Acknowledgement Letter
 AD = (Discipline) Adequate
 IN = (Discipline) Inadequate
 AM = Amendment

1st Cycle Original w/ Mid-cycle Major Amendment

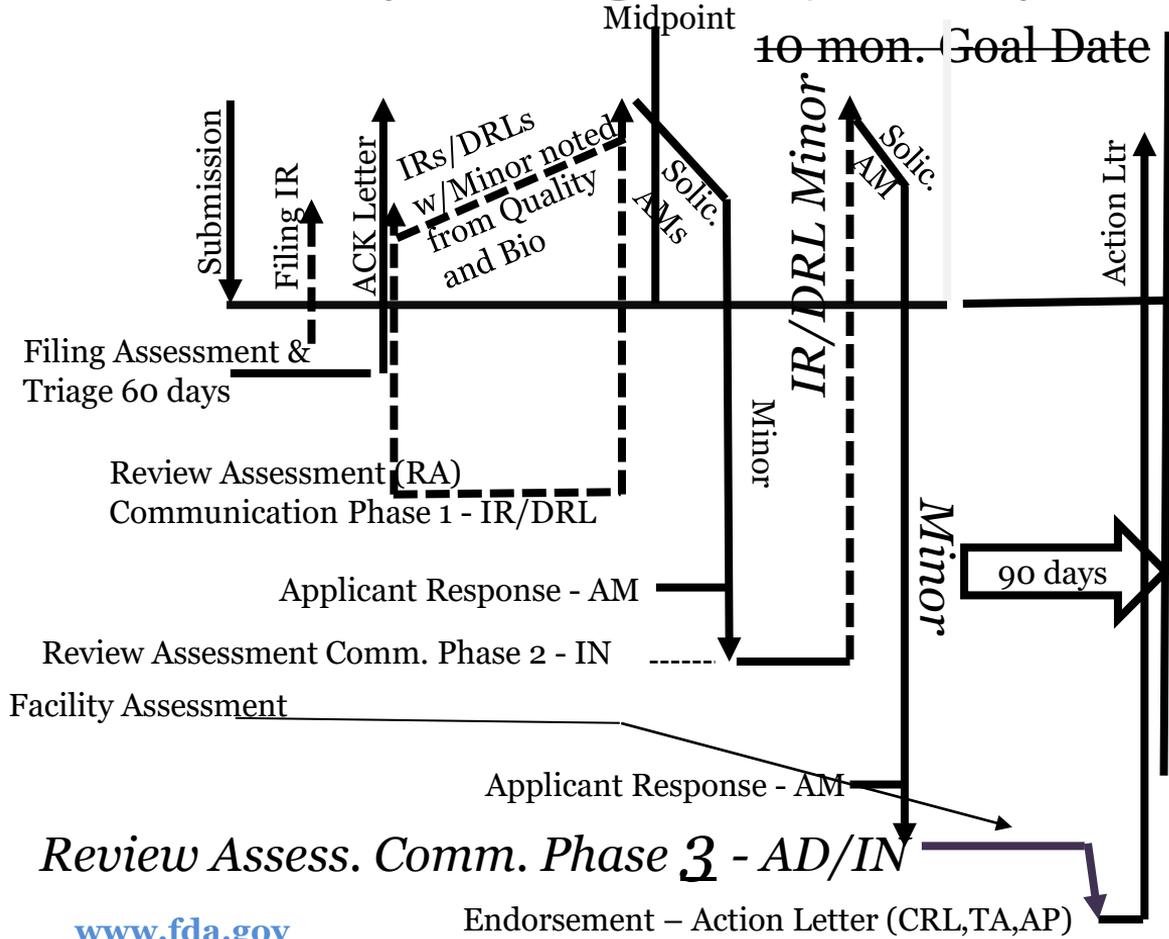


Up to 6, 8, or 10 months extension to goal date from the time of submission (BUT most likely a few months less since trigger is Major Amendment submission sent to FDA around month 7)

- Tips:
1. Respond on time
 2. Thorough response
 3. Alert discipline PM of issues

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1st Cycle Original w/Late Cycle-IR/DRL



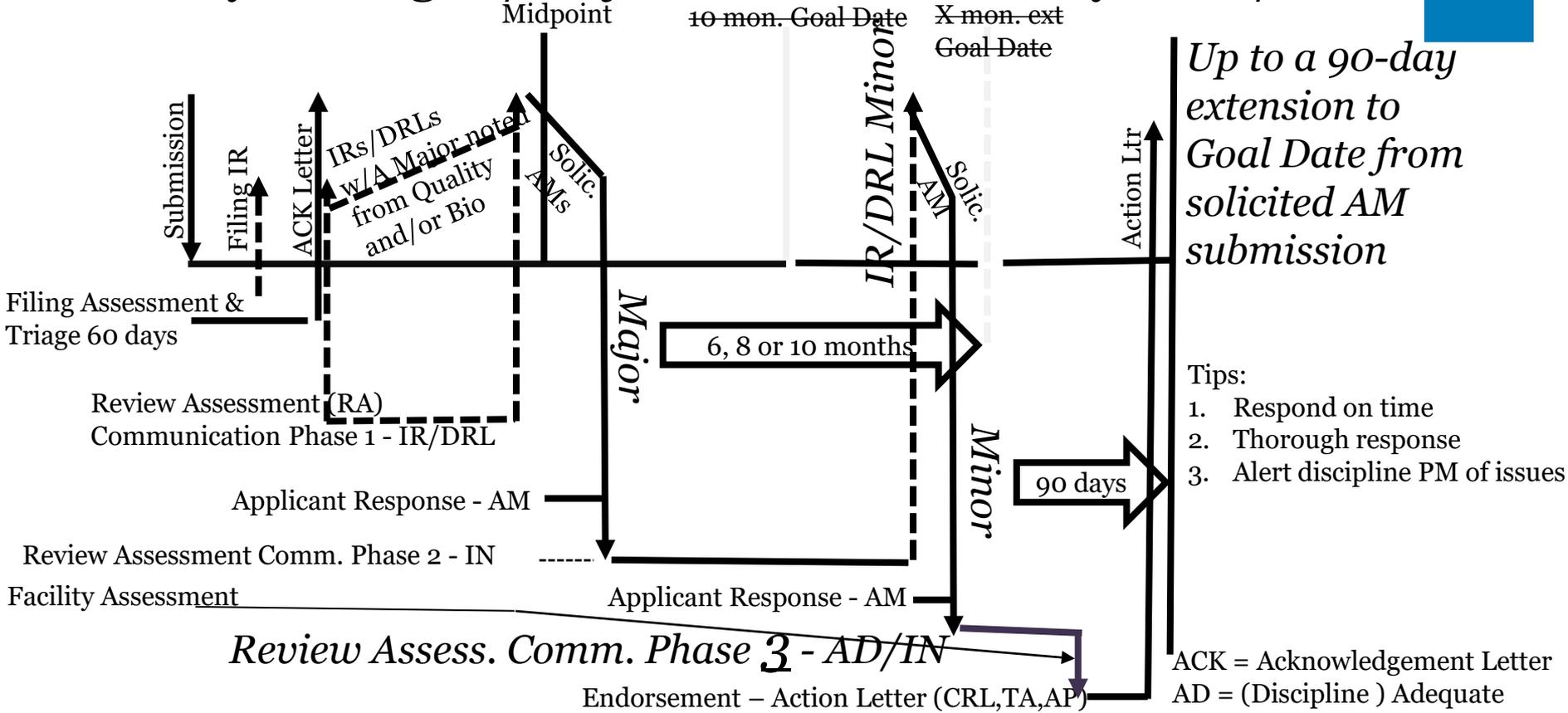
Up to a 90-day extension to Goal Date from Solicited AM submission

Tips:

1. Respond on time
2. Thorough response
3. Alert discipline PM of issues

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1st Cycle Orig. w/Major Amend. & Late-Cycle IR/DRL

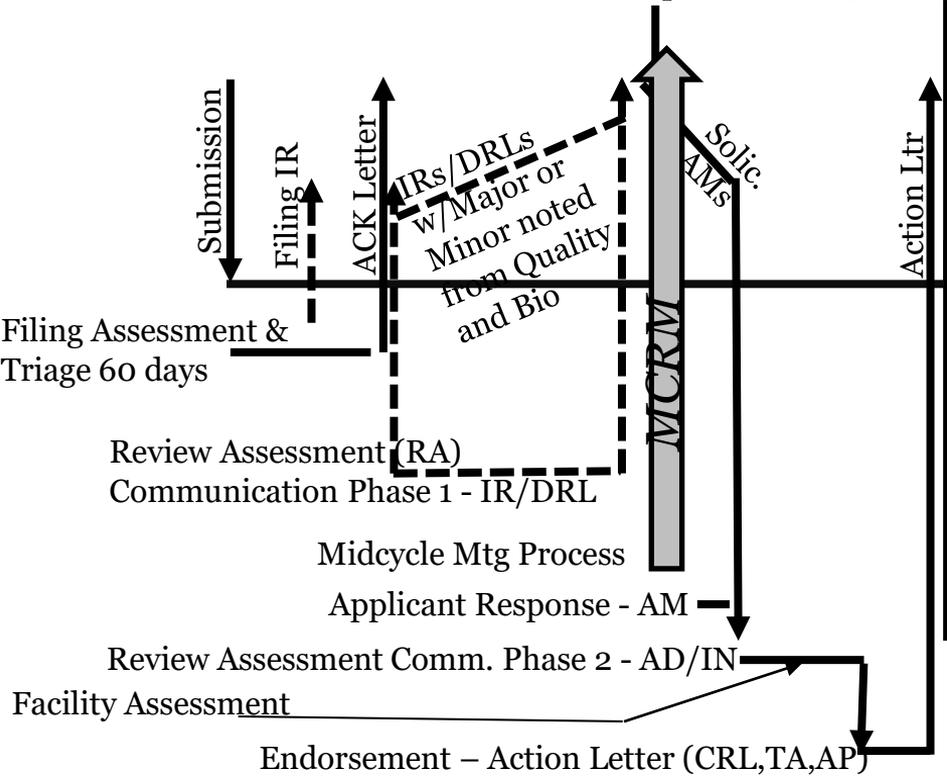


- Tips:
1. Respond on time
 2. Thorough response
 3. Alert discipline PM of issues

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1st Cycle Original w/MCRM

Midpoint 10 mon. Goal Date



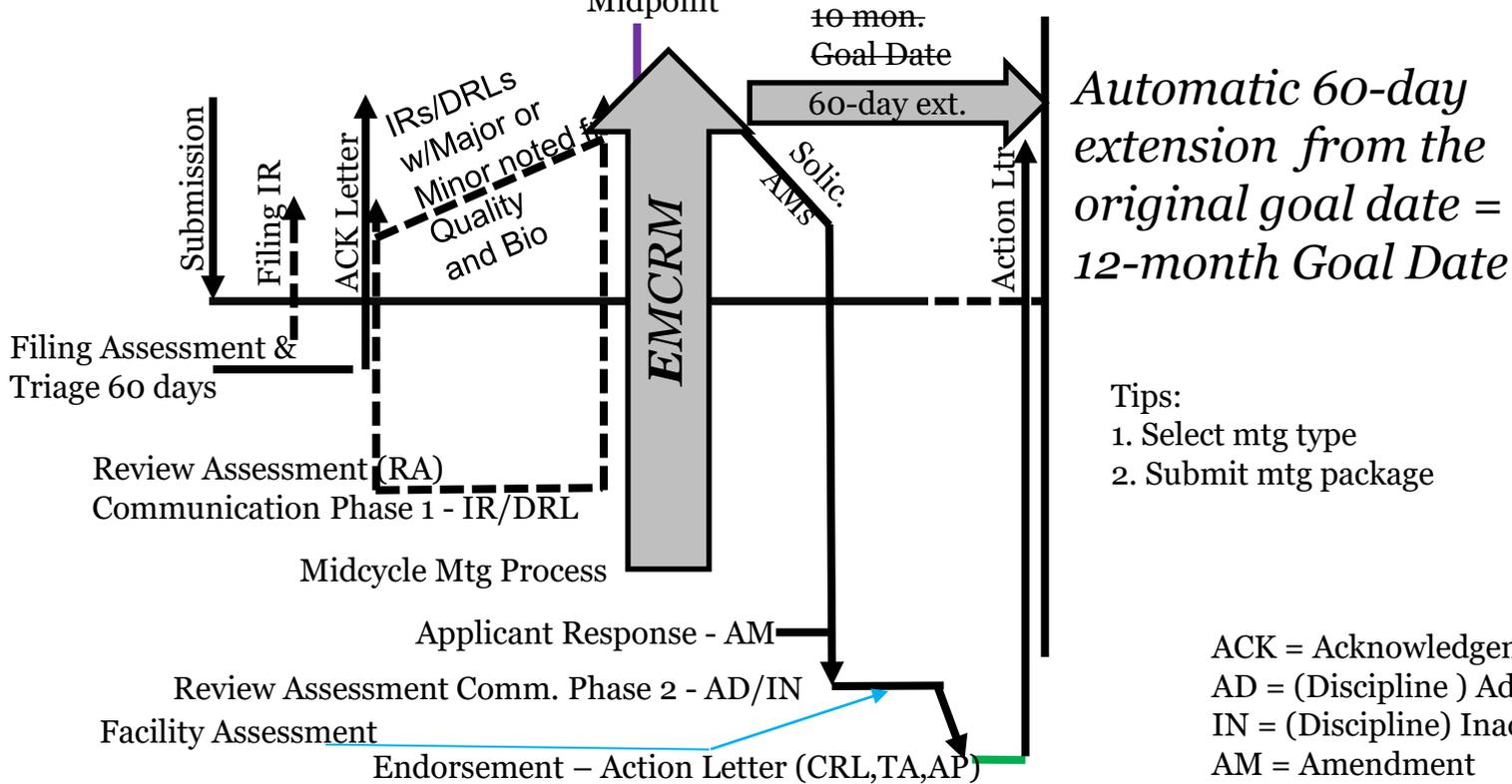
MCRM = Mid-Cycle Review Meeting

No change to goal date

- Tips:
1. Select mtg type
 2. Submit mtg package

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1st Cycle Original w/*EMCRM*



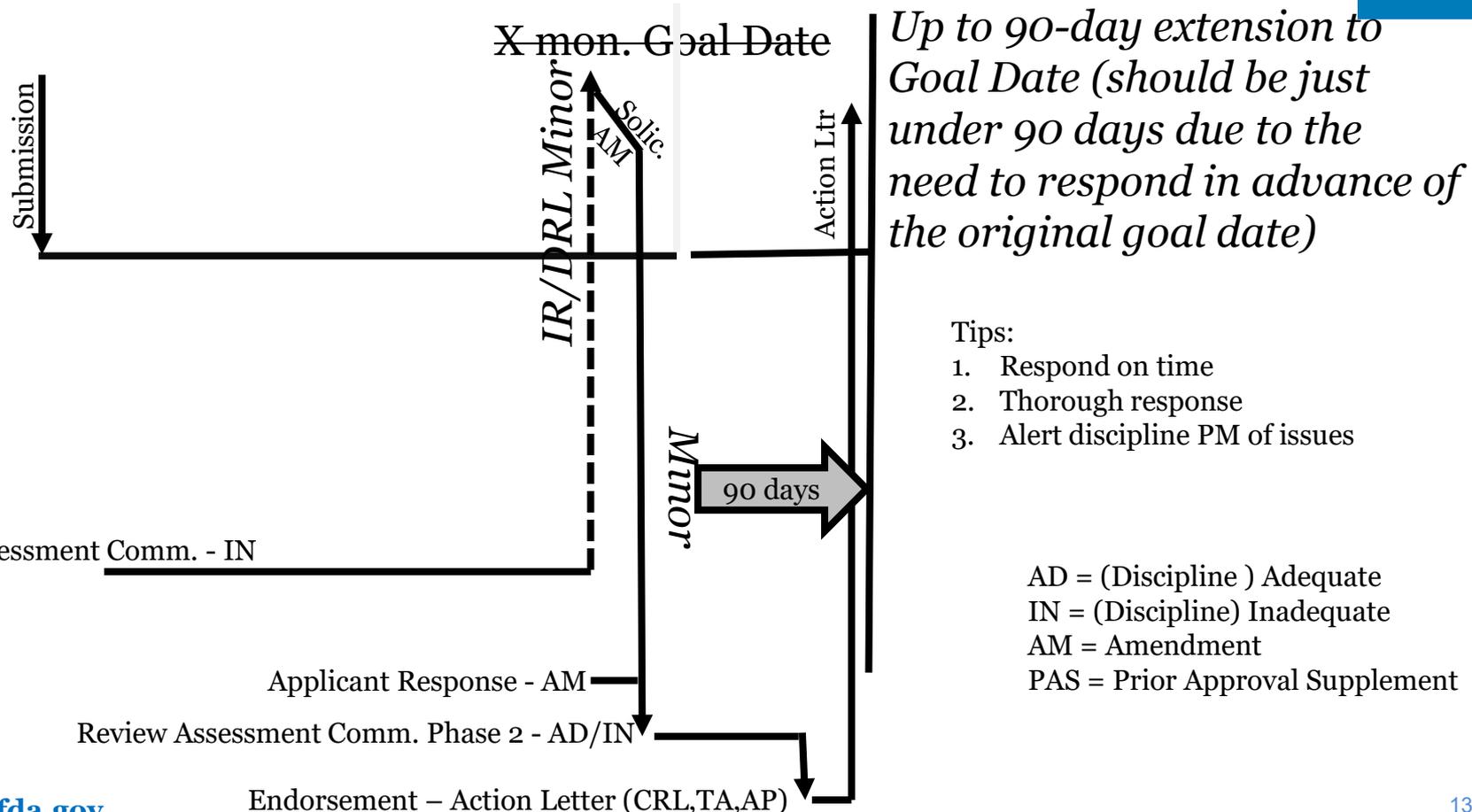
Automatic 60-day extension from the original goal date = 12-month Goal Date

- Tips:
1. Select mtg type
 2. Submit mtg package

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EMCRM = **Enhanced** Mid-Cycle Review Meeting

Subsequent Cycle Original w/ IR/DRL

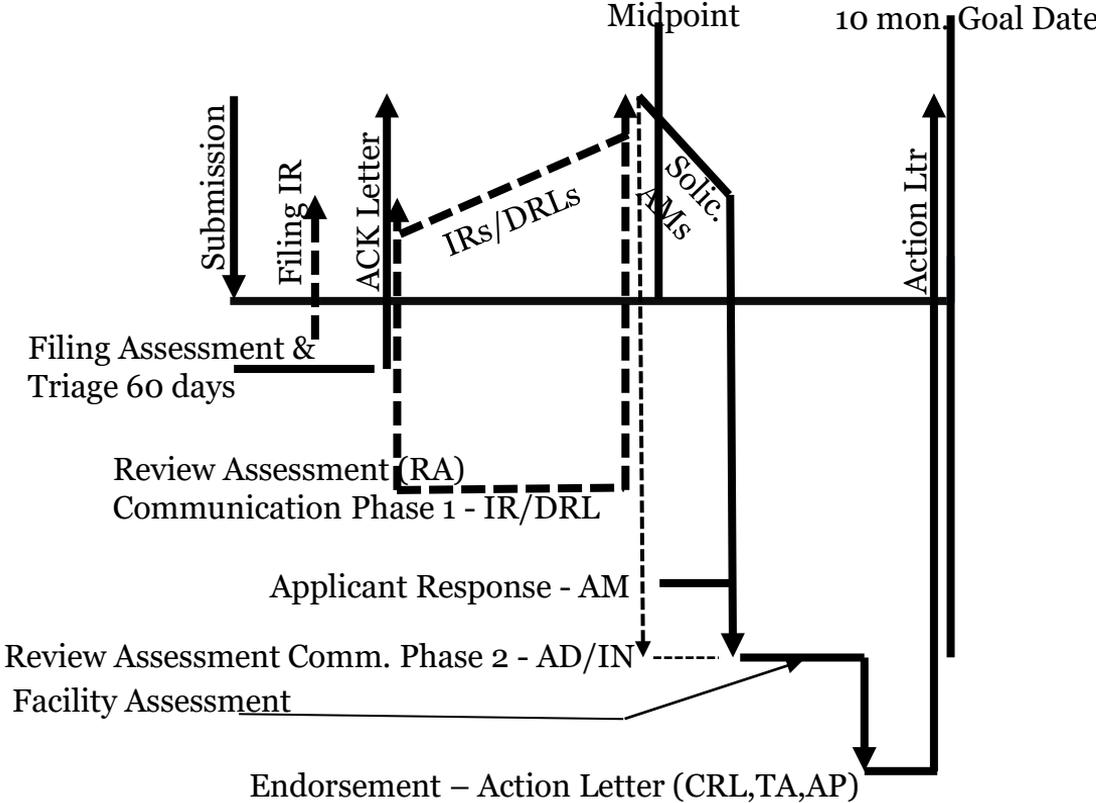


Facility Not Ready

Facility Not Ready (at time of orig. sub.)

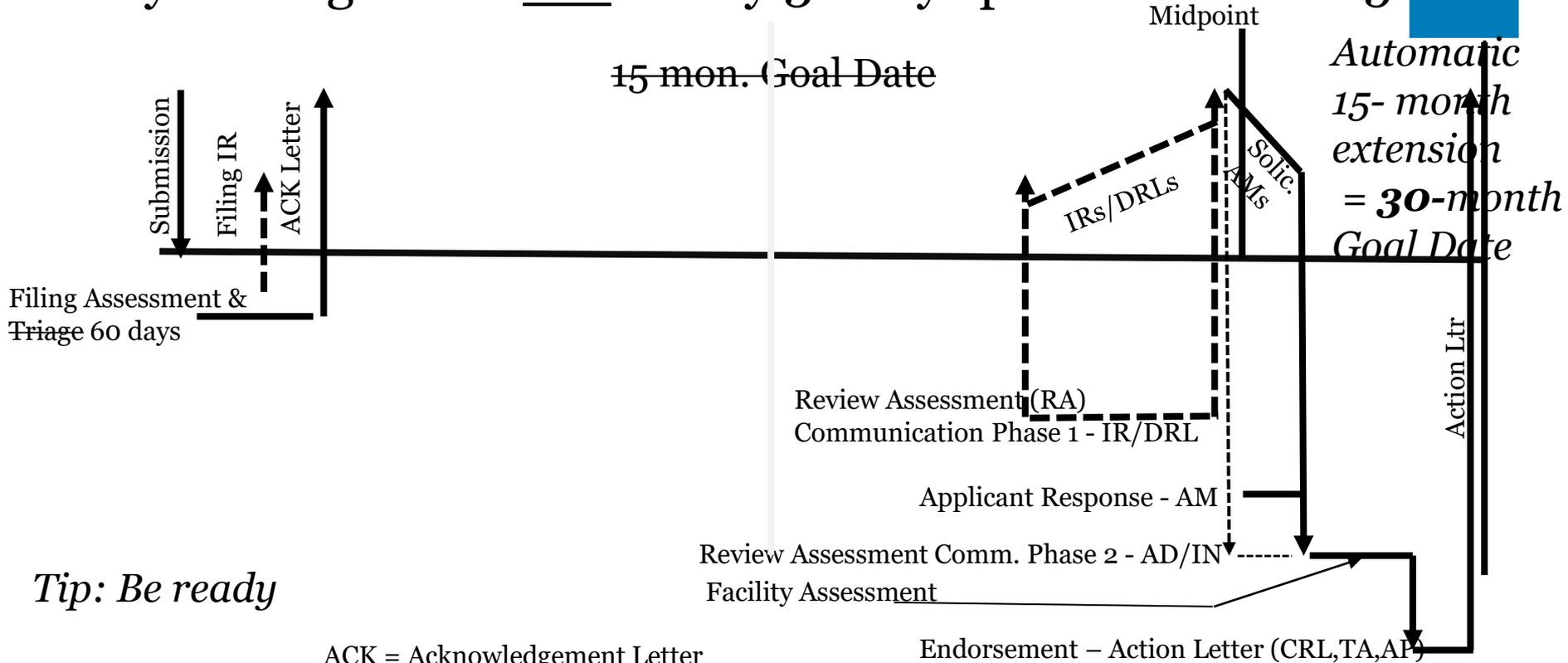
- 1st Cycle Original ANDA from GDUFA II
- Facility still not ready by month 14 – original 15-month goal date extended
- Facility ready at month 10 – original 15-month goal extended
- Facility ready at month 3 – original 15-month goal date reduced

1st Cycle Original from GDUFA II



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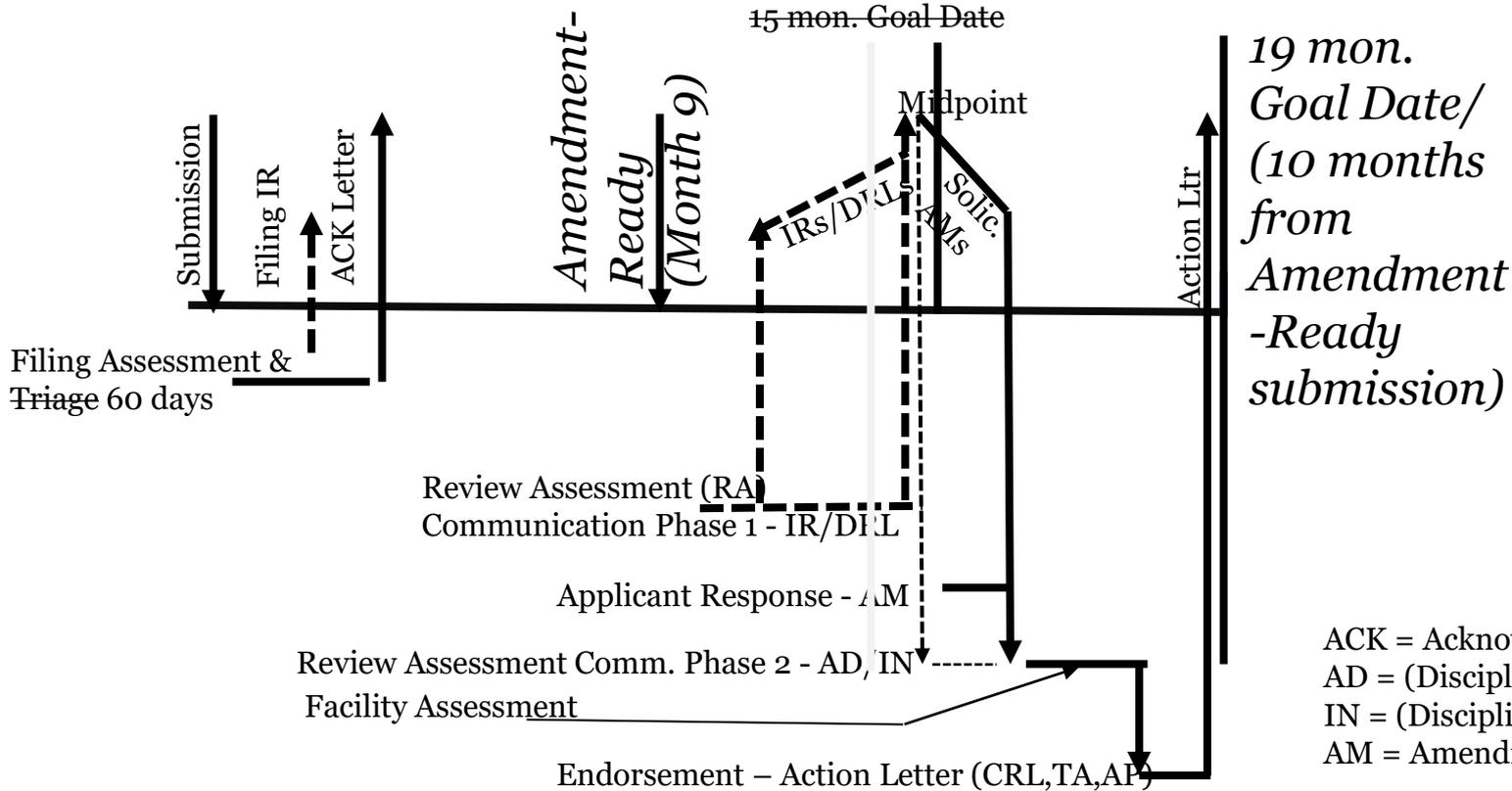
1st Cycle Orig. Facil. Not Ready 30 days prior to month 15



Tip: Be ready

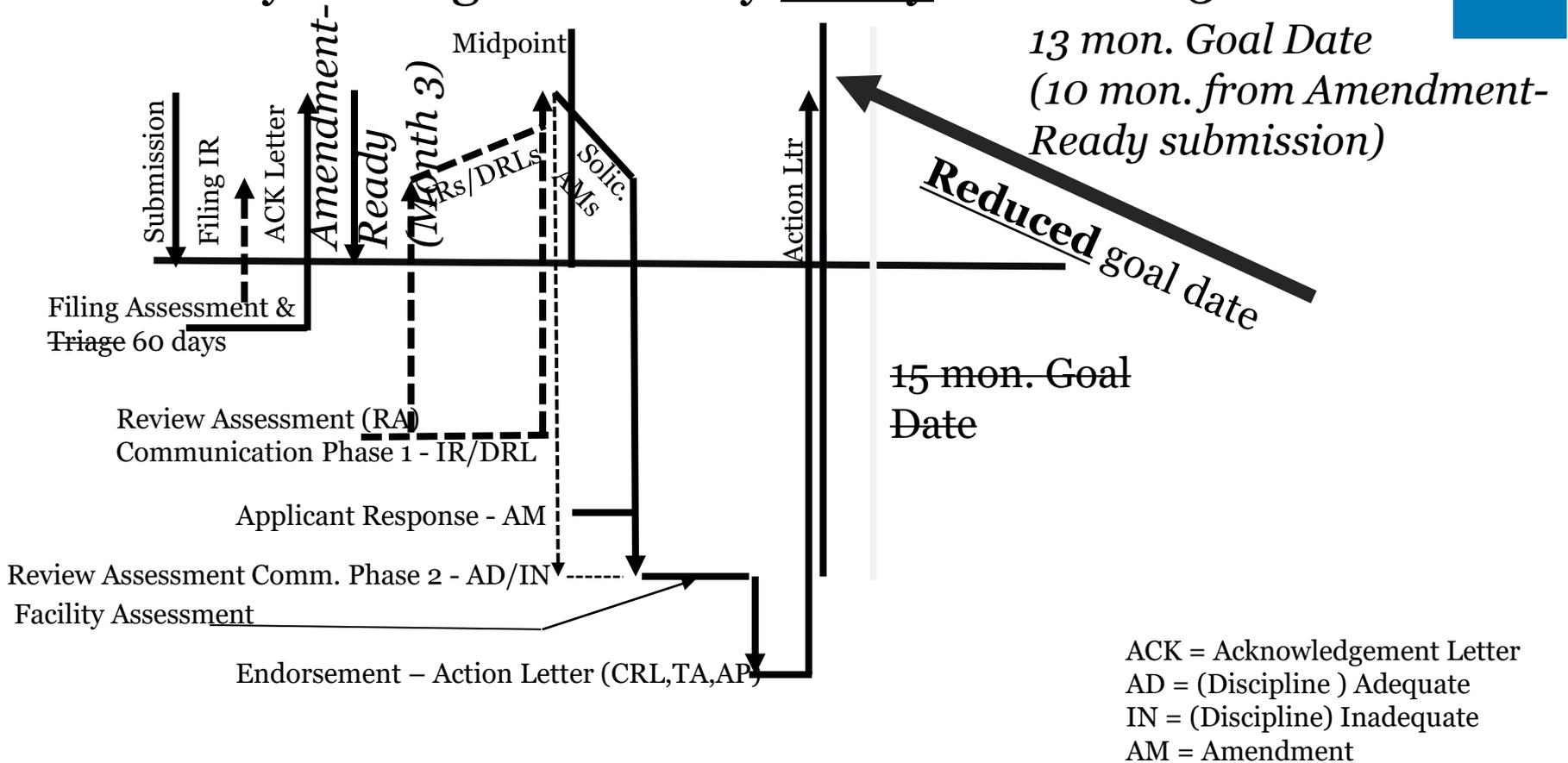
- ACK = Acknowledgement Letter
- AD = (Discipline) Adequate
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1st Cycle Original Facility Ready at Month 9



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1st Cycle Original Facility Ready at Month 3



Imminent Action

(formerly Imminent Approval)

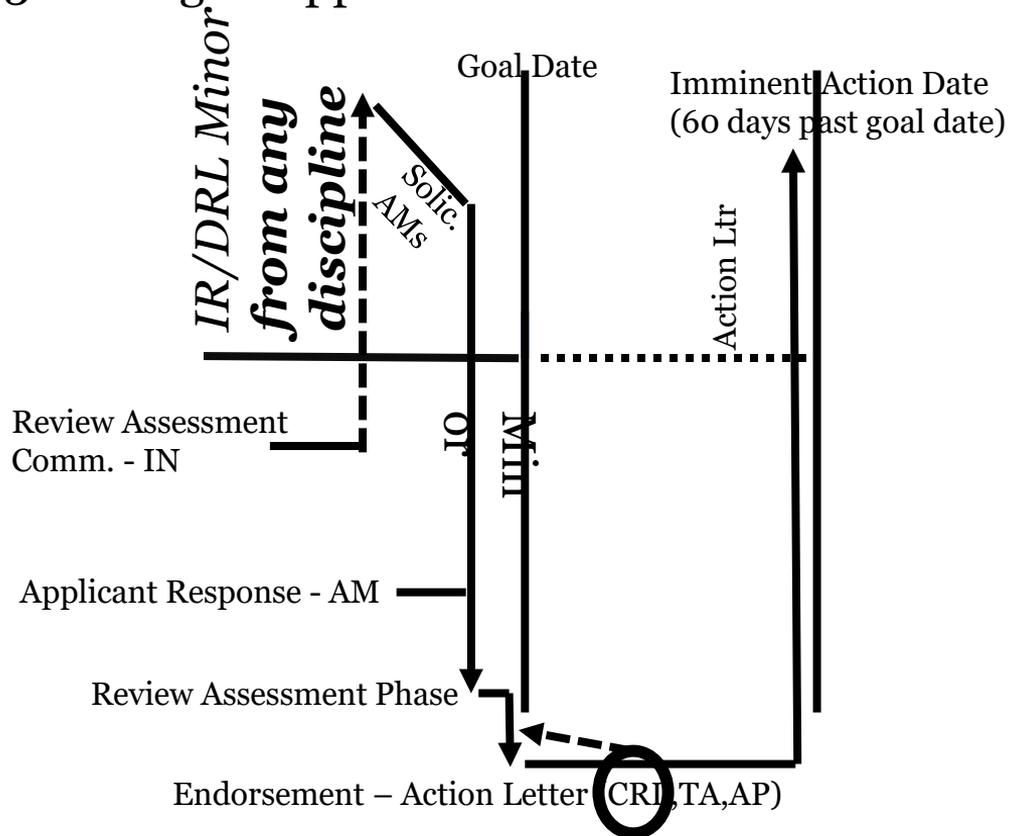
1. Skipping a Tentative Approval (TA) by the goal date to facilitate full Approval (AP) within 60 days after the goal date



2. AP or TA an application submitted by a first applicant by the 30-month forfeiture date

Imminent Action (cont.)

3. Bring an application with one or more small issues to AP or TA



Tips:

1. Respond on time
2. Thorough response
3. Alert discipline PM of issues w/ IR/DRL response
4. Contact RPM for ANDA status questions

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 IN = (Discipline) Inadequate
 AM = Amendment

Concluding Remarks

- Lots of changes with goal dates
- Increased opportunities for 1st cycle approvals!
- Increased opportunities for current cycle approvals!

Original Application Contacts

- IR/DRL issues – respective discipline Project Manager (called Regulatory Business Project Manger for quality/Office of Pharmaceutical Quality)
- Application status & Imminent Action process – Regulatory Project Manager in the Division of Project Management

Thank you!



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