

GDUFA II Goals Integration

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What is New/Changed?

- 8 month goal for priority applications with successful Pre-submission Facility Correspondence (PFC)
- Mid-point Information Request (IR)/Discipline Review Letter (DRL)
- Mid-review-cycle t-con for ANDAs in the Pre-ANDA Program...for Complex Products

What Does it Mean?

- ***Shorter goals*** for priority original applications where applicants put the effort into developing their products and related facilities and utilizing the PFC process
- ***More communications*** during the goal period

Day 0/receipt



Day 0/receipt

Filing Decision
30-60 days



Day 0/receipt

Filing Decision
30-60 days

8/10 months

Day 0/receipt

Filing Decision
30-60 days

Midpoint

8/10 months



Day 0/receipt

Filing Decision
30-60 days

Midpoint

+ 1 Mon.

8/10 months



Day 0/receipt

Filing Decision
30-60 days

Midpoint

+ 1 Mon.

GDUFA Date 8/10 months



Day 0/receipt

Filing Decision
30-60 days

Midpoint

MCD DRL/T-con + 1 Mon.

GDUFA Date 8/10 months



Day 0/receipt

Filing Decision
30-60 days

Midpoint

MRD meet MCD

MCD DRL/T-con + 1 Mon.

GDUFA Date 8/10 months



Day 0/receipt

Filing Decision
30-60 days

DRD

Midpoint

MRD meet MCD

MCD DRL/T-con + 1 Mon.

GDUFA Date 8/10 months



Day 0/receipt

Filing Decision
30-60 days

Rev. Phase 1

DRD

Midpoint

MRD meet MCD

MCD DRL/T-con + 1 Mon.

GDUFA Date 8/10 months



Day 0/receipt

Filing Decision
30-60 days

Consult Issuance

Rev. Phase 1

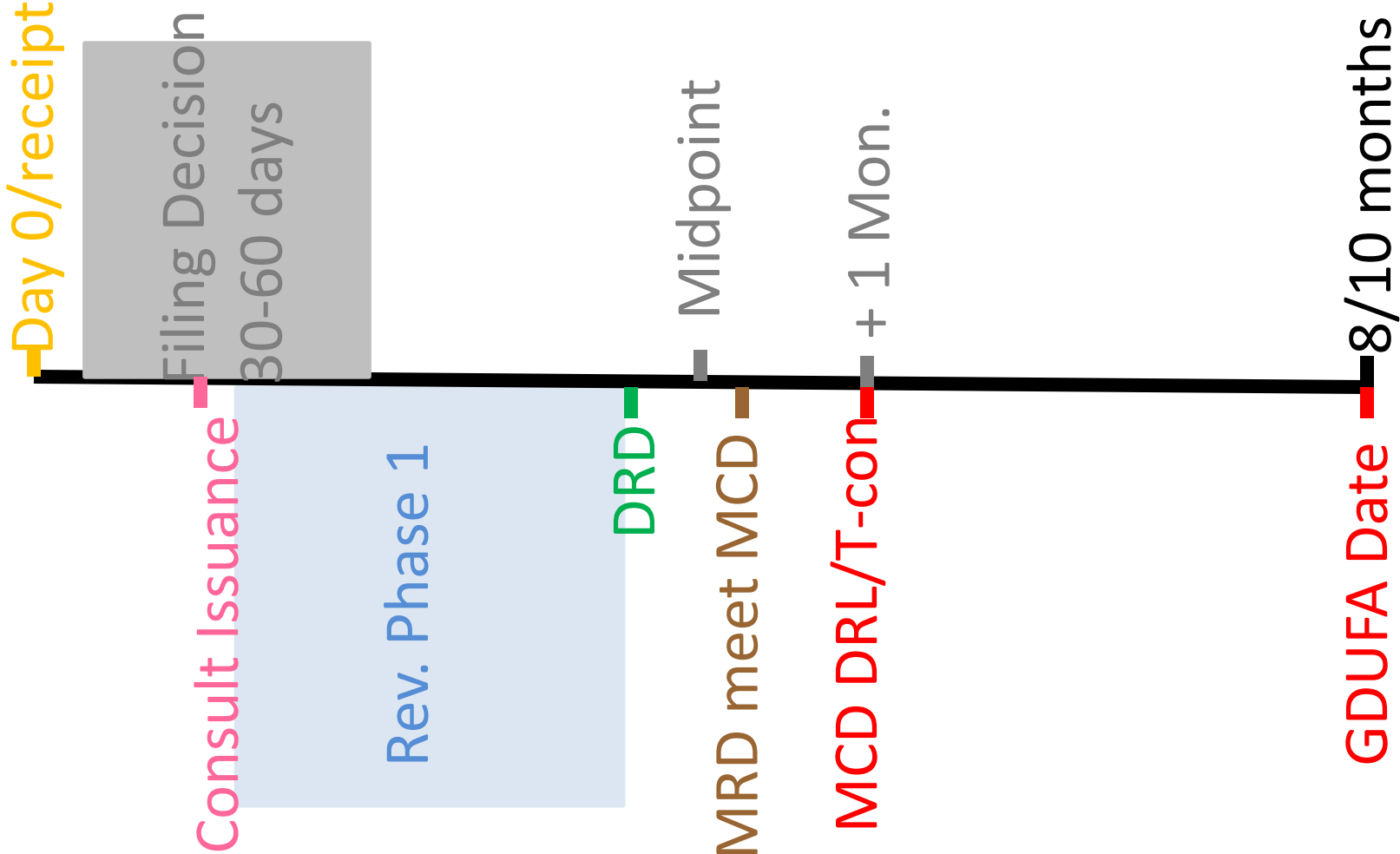
DRD

Midpoint

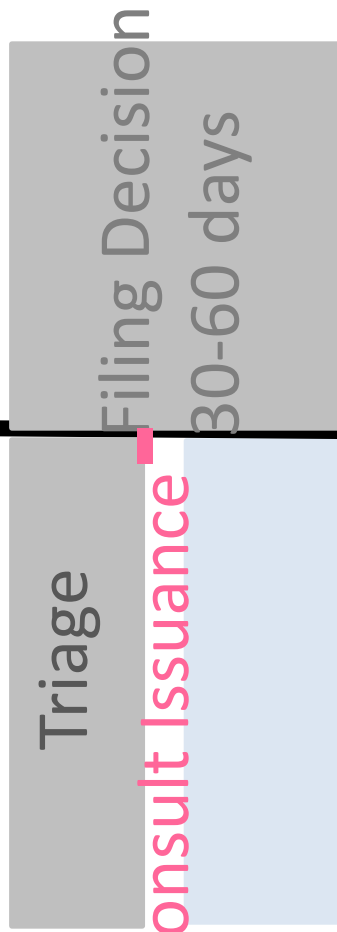
MRD meet MCD

MCD DRL/T-con + 1 Mon.

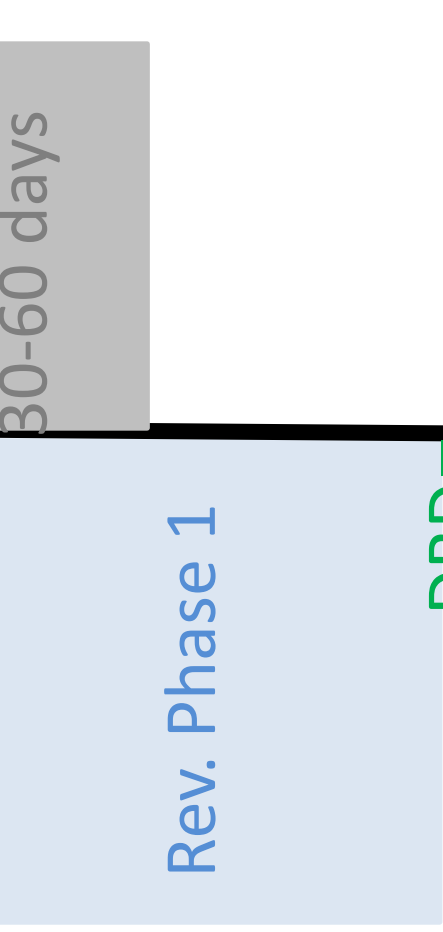
GDUFA Date 8/10 months



Day 0/receipt



Consult Issuance



DRD

Midpoint

MRD meet MCD

MCD DRL/T-con + 1 Mon.

GDUFA Date 8/10 months

Day 0/receipt

Triage

Filing Decision
30-60 days

Consult Issuance

Rev. Phase 1

1st IR

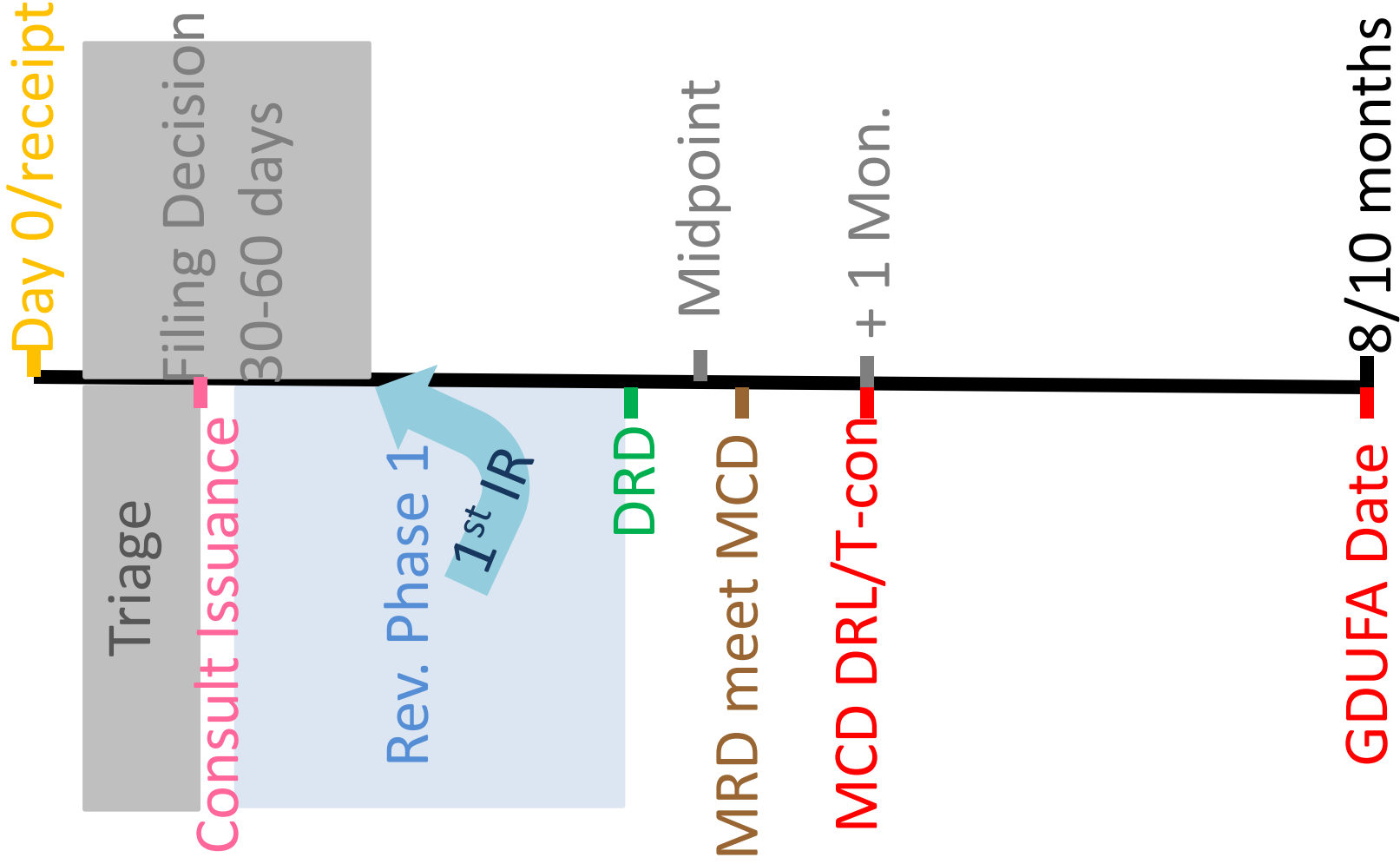
DRD

Midpoint

MRD meet MCD

MCD DRL/T-con + 1 Mon.

GDUFA Date 8/10 months



Day 0/receipt

Triage

Filing Decision
30-60 days

Consult Issuance

Rev. Phase 1

1st IR

DRD

Midpoint

MRD meet MCD

MCD DRL/T-con + 1 Mon.

Amendment

GDUFA Date 8/10 months

Day 0/receipt

Triage

Filing Decision
30-60 days

Consult Issuance

Rev. Phase 1

1st IR

DRD

Midpoint

MRD meet MCD

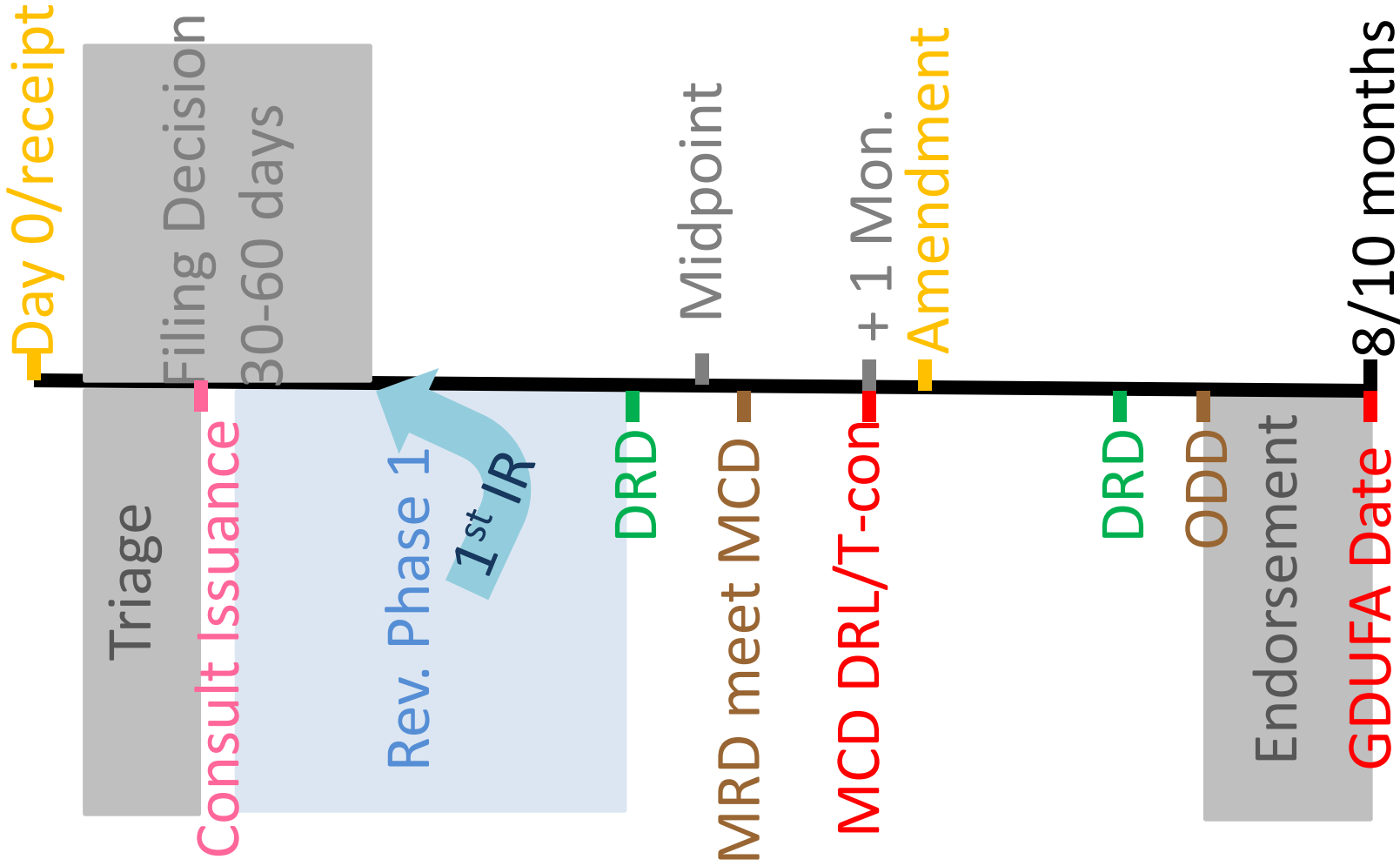
MCD DRL/T-con + 1 Mon.

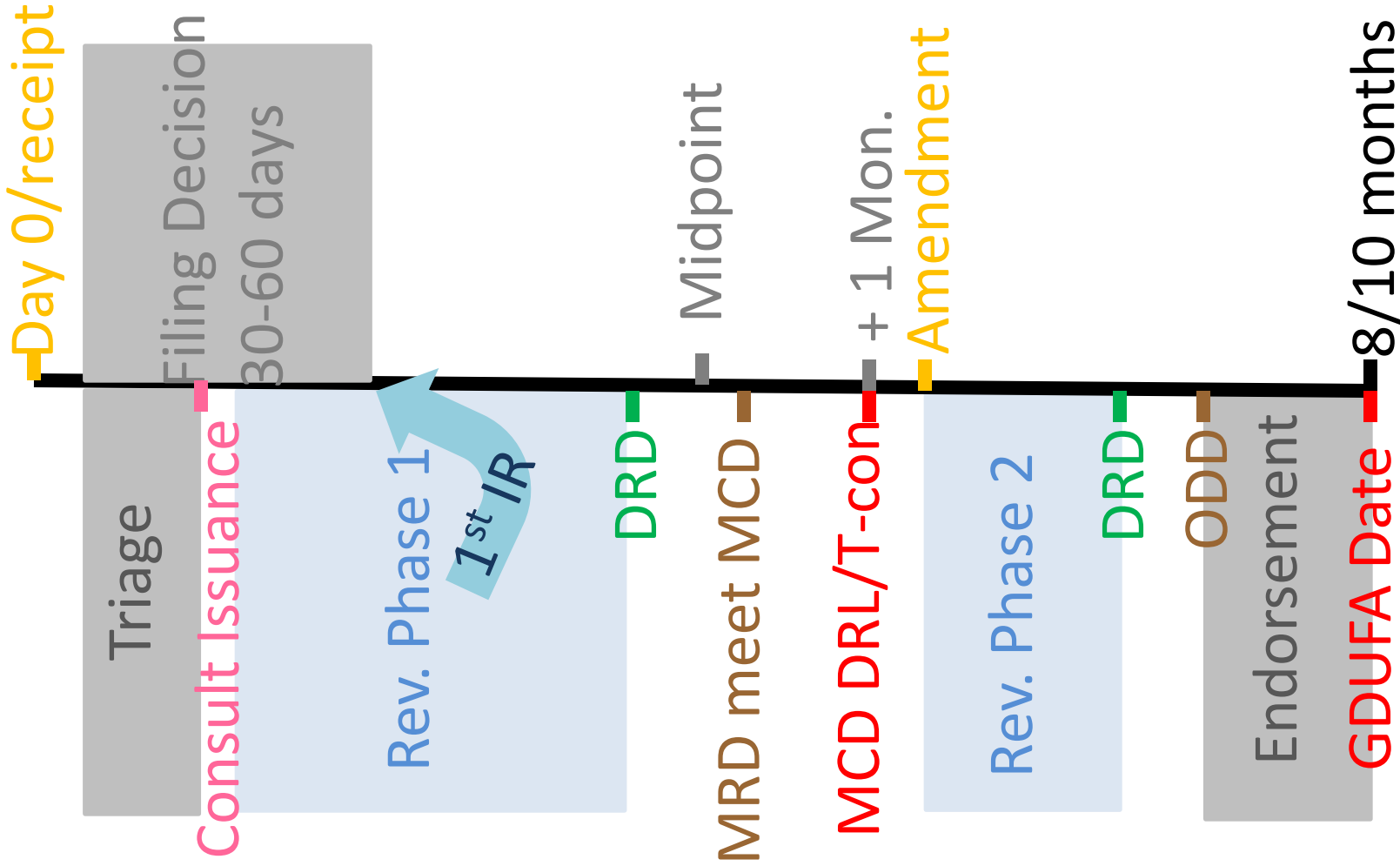
Amendment

ODD

Endorsement

GDUFA Date 8/10 months





Review Definitions

- **Discipline Review Letter (DRL)** – communication of *at least the primary reviewer's thoughts* on the application
- **Discipline Review Date (DRD)** – tool for managers to use to provide reviewers clarity on when primary reviews are needed; controlled by the discipline (aka task date)
- **Mid-Review Date (MRD)** – date all discipline reviews should be turned over to the discipline PMs for inclusion in the DRL; controlled by the discipline

Review Definitions (cont.)

- **Mid-cycle Date (MCD)** – GDUFA II mid-point plus 1 month goal (priority ANDA 5 months & standard ANDA 6 months) for communicating the primary reviewer's thoughts to the applicant; controlled by the Commitment Letter (RPM can adjust for unsolicited amendments)
- **Mid-review Cycle T-con** – CDER initiated t-con w/applicant to discuss review thoughts, needs, clarifications, etc.; coordinated by the RPM and conducted by the MCD; for **Pre-ANDA...Complex Program meeting applications only**

Review Definitions (cont.)



- **Owner Due Date (ODD)** – date *all reviews* need to be **complete** to allow action letter (CR, AP, TA) issuance in advance of the GDUFA II goal; controlled by the owner:
 - For original ANDA – turned over to the RPM
 - For cross cutting PAS submissions – turned over to RPM
 - For labeling only PAS submissions – turned over to Labeling PM
 - Quality only PAS submissions – turned over to the OPQ RBPM

PFC

Day 0/receipt

Consultance

Filing Decision
30-60 days

Rev. Phase 1
1st IR

DRD

Midpoint

MCD

+ 1 Mon.

Amendment

Rev. Phase 2

DRD

ODD

Endorsement

GDUFA Date 8/10 months

Facility Assess.

Linkage to final review decision

What is the Impact?

- Increased ***business certainty*** as review times and communications are well defined
- Opportunity for applicants doing it right to make minor updates, corrections, etc. & ***gain a one cycle approval - win for FDA & firm!***

Who is Responsible?

- **Applicants** to submit PFCs
- **Applicants** to identify appropriate prioritization request for **ANDA *and* now PFC** basis using MAPP 5240.3
- **Applicants** to submit an ANDA that is accepted
- **Division of Filing Review** priority assessment and goal setting

What Will They Do?

- **Division of Filing Review** will assess:
 - ANDA warrants priority
 - PFC found adequate by OPQ and OTS
 - ***Facilities info basically unchanged in ANDA***
 - ANDA submitted at least “60 days” after PFC
 - Submission for filing (*unchanged*)

How Will it be Evaluated?

- Prioritization:
 - Decisions require secondary validation
 - Enhanced Platform tracking
- Goals:
 - Discipline PM/RPBM and RPM monitoring
 - Enhanced Platform tracking
- ***Formal reporting of success!***

What Can Industry Do to Assist?

- Submit complete and clear PFCs and ANDAs
- Clearly note in the PFC and ANDA that you are requesting a priority goal and justify it
- Clearly note in ANDA if part of Pre-ANDA Program
- Provide **complete** and quick responses to IRs/DRLs

What Can Industry Do to Assist? (cont.)

- ***Champion your own ANDA***
 - Use good contractors (DMFs, etc.)
 - Communicate with contractors (both ways)
 - Consider the timing of changes
 - Watch for external changes (RLD, USP, etc.)

Resources

- *Watch for additional guidances and MAPPs*
- *ANDAs: Pre-Submission Facility Correspondence Associated with Priority Submissions (Guidance)*
- *Prioritization of the Review of Original ANDAs, Amendments, and Supplements (MAPP 5240. 3)*

Resources (cont.)

- *ANDA Submissions — Content and Format of Abbreviated New Drug Applications* (Guidance)
- *ANDA Submissions – Refuse-to-Receive Standards* (Guidance)
- *Information Requests and Discipline Review Letters Under GDUFA* (Guidance)

External Contact

- ANDA questions – start with **your Regulatory Project Manager (RPM)**
- IR/DRL questions or delays in responding – start with your discipline PM (RBPM for OPQ/quality)

