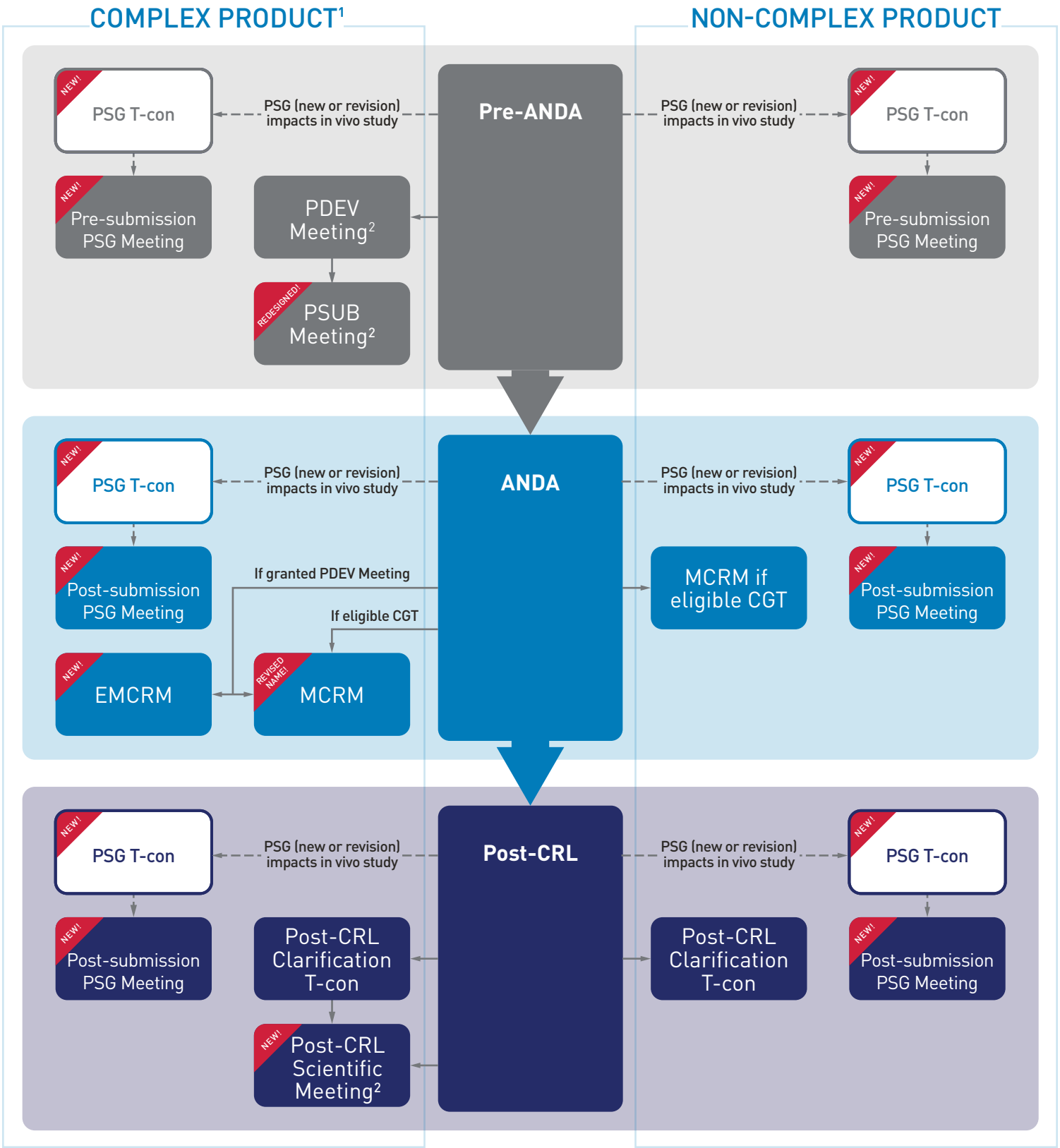
GDUFA III Commitment Letter | Summary of T-cons & Meetings

Changes with GDUFA III on and after October 1, 2022. This infographic shows a high-level overview of various T-cons and meetings including new and redesigned ones based on ANDA stage and drug product complexity.



Pre-ANDA

	"Pre-submission" PSG T-Con NEW!	Pre-submission PSG Meeting NEW!	PDEV Meeting	PSUB Meeting REDESIGNED!
Eligible Products	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex[7]	Complex with PDEV meeting[8]
When to Request a Meeting	When a new or revised PSG is published and a prospective applicant has already commenced an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or CRO)	Following PSG T-con, meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG	No PSG, or new alternative BE method different from PSG recommendation	To present unique or novel data or information that will be included in the ANDA submission
Format of the Meeting	T-Con[3]	In Person FTF[5] or VC[6]	In Person FTF[5] or VC[6]	In Person FTF[5] or VC
Grant/Deny Decision Timeline	14 days	14 days	14 days	30 days
Days to Conduct the Meeting	30 days from meeting request receipt	120 days from meeting request receipt	120 days from meeting being granted	60 days from meeting request receipt
When to Send CC[4] in Lieu of a Meeting Request	When a CC could adequately address the prospective applicant's questions or when the prospective applicant's clarification or scientific questions are outside of the scope of the meeting type In addition, applicants can send CC after meetings if they are seeking further clarification or have new questions			

ANDA

	"Post-submission" PSG T-Con NEW!	Post-submission PSG Meeting NEW!	MCRM REVISED NAME!	EMCRM NEW!
Eligible Products	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex with PDEV meeting; CGTs	Complex with PDEV meeting
When to Request a Meeting	When a new or revised PSG is published and an applicant has already commenced an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or CRO)	Following PSG T-con, meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG	Applicant has questions about the rationale for any deficiency identified in the mid-cycle DRL(s), and/or clarification questions related to FDA's assessment of the data or information in the ANDA[9]	Applicant has questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s) and/or questions about potential new data or information to address any possible deficiencies identified in the mid-cycle DRL(s)[9]
Format of the Meeting	T-con[3]	In Person FTF[5] or VC[6]	T-con[3]	In Person FTF[5] or VC[6]
Grant/Deny Decision Timeline	14 days	14 days	14 days	14 days
Days to Conduct the Meeting	30 days from meeting request receipt	90 days from meeting request receipt	30 days from meeting request receipt	90 days from last mid-cycle DRL issuance
When to send CC[4] After Meeting	If the applicant seeks further feedback from FDA following the PSG T-con	Not Applicable	Not Applicable	Not Applicable

Post-CRL

	"Post-submission" PSG T-Con NEW!	Post-submission PSG Meeting NEW!	Post-CRL Clarification T-Con	Post-CRL Scientific Meeting NEW!
Eligible Products	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex if PSG (new or revision) impacts in vivo BE study	Complex and non-complex	Complex[10]
When to Request a Meeting	When a new or revised PSG is published and an applicant has already commenced an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or CRO)	Following PSG T-con, meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG	Within 10 days of CRL issuance to get 30-day goal date; to seek clarification concerning deficiencies identified in a CRL	Seek FDA's scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence (must discuss at least one of the 4 types outlined in section IV.C.1.a of the GDUFA III Commitment Letter)
Format of the Meeting	T-con[3]	In Person FTF[5] or VC[6]	T-con[3]	In Person FTF[5] or VC[6]
Grant/Deny Decision Timeline	14 days	14 days	14 days	14 days
Days to Conduct the Meeting	30 days from meeting request receipt	90 days from meeting request receipt	30 days from meeting request receipt	90 days from meeting being granted
When to send CC[4] In Lieu of a Meeting Request	When a CC could adequately address the applicant's questions or when the applicant's clarification or scientific questions are outside of the scope of the meeting type In addition, applicants can send CC after meetings if they are seeking further clarification or have new questions			

General Notes:

- FDA may grant meetings to applicants in situations beyond those described in the GDUFA III commitment letter at its discretion, and in doing so generally considers the workload and availability of staff and anticipated value to the ANDA assessment process.
- Days means calendar days in the tables above.

[1] Information on which drug products are considered complex can be found in the GDUFA III commitment letter and the CDER MAPP 5240.10 *Classifying Approved New Drug Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes*.

[2] Meeting requests for non-complex products may be granted in some situations. See Footnotes 7, 8 and 10.

[3] WR can be provided if requested or agreed to by the applicant.

[4] FDA's goals are to respond to Level I CC within 60 days and Level II CC within 120 days.

[5] "In Person FTF" is the FTF meeting as described in the Guidance for Industry: "Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA" (October 2022) that is conducted in a hybrid format where some attendees participate in person at the FDA and remaining participate via VC. Beginning March 2023, FDA will resume in-person, face-to-face (FTF) meetings with industry in a phased-in approach. Initially, the in-person FTF meeting option will only be granted for PDEV and PSUB meetings for which the applicant requests the in-person FTF meeting format. Other GDUFA meetings, if granted, will be held fully virtually (e.g., as a VC), even if the applicant requests an in-person, FTF format.

[6] FDA may provide a T-con or WR, if requested by the applicant or if the meeting is granted at FDA's discretion.

[7] A PDEV meeting may be granted for a non-complex generic product if, in FDA's judgment, the prospective applicant submits a complete meeting package, a controlled correspondence would not adequately address the prospective applicant's questions, and the meeting would significantly improve ANDA assessment efficiency.

[8] A PSUB meeting may be granted for applicants who were not granted a PDEV meeting for the same complex generic product or for a non-complex generic product if FDA believes in its sole discretion that the PSUB meeting would improve assessment efficiency.

[9] Applicants have 7 days from receipt of the last mid-cycle DRL to submit a request for an MCRM or EMCRM.

[10] A post-CRL scientific meeting may be granted for a non-complex generic product if in FDA's judgement the request raises issues that are best addressed via this meeting process and cannot be adequately addressed through CC.

Abbreviation	Meaning
ANDA	Abbreviated New Drug Application
BE	Bioequivalence
CC	Controlled Correspondence
CGT	Competitive Generic Therapy
CRL	Complete Response Letter
DRL	Discipline Review Letter
EMCRM	Enhanced Mid-Cycle Review Meeting
FTF	In-person, Face-to-Face Meeting
GDUFA	Generic Drug User Fee Amendments
MCRM	Mid-Cycle Review Meeting
PDEV	Product Development
PSG	Product-Specific Guidance
PSUB	Pre-Submission
T-con	Teleconference
VC	Videoconference
WR	Written Response