Communication Tool Selection

Are you ready for agreement on your product development plan for one or more technical sections?

NO

What type of engagement?

None

A-0000 (no EI)

Quick question

Email or Informal Communication (Z)

Substantial data to support development plan

A-0000 (w/EI) or H

Meeting to discuss

Other ONAPE Meeting (OO)

Do you need additional feedback?

YES

NO

Return to the top if you need additional feedback in the future

YES

Do you need binding agreement?

NO

Do you have a previously agreed-upon development plan or is this a B1 supplement?

YES

Do you want written feedback only?

YES

Proposed Development Plan Submission (C)

NO

Do you want to meet in person?

NO

Do you want the option for written communication only?

YES

Early Response Letter w/ optional Virtual Presubmission Conference (PS)

NO

YES

Presubmission Conference (PS)

YES

Do you need additional feedback?

YES

NO

Product development plan established

P&P 1243.4000 Processing A Request To Open An Investigational (INAD) Or Generic Investigational New Animal Drug (JINAD) File

A-0000 Required Information:

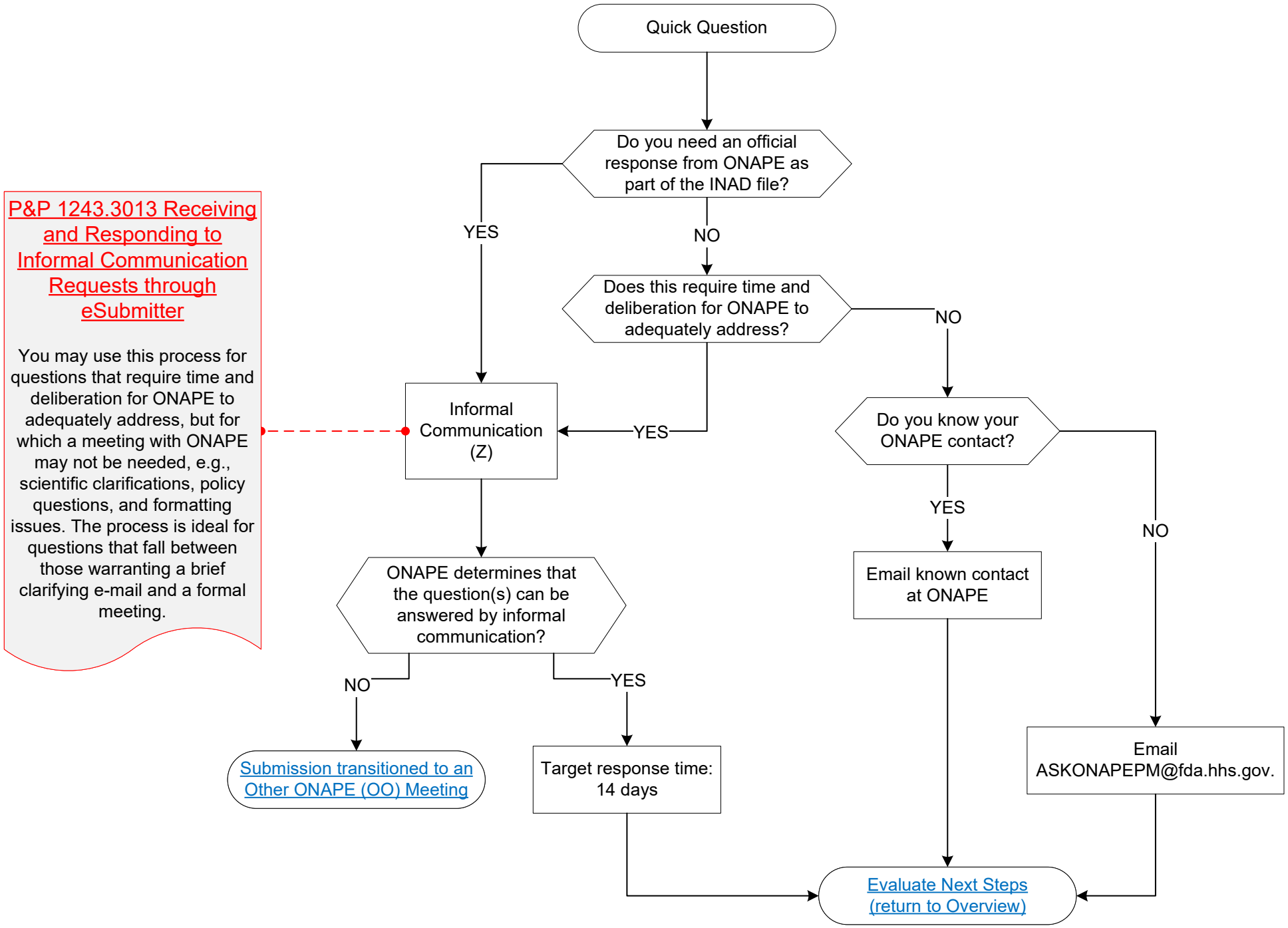
Sponsor info
Drug ID
Target Species
Dosage
Indication

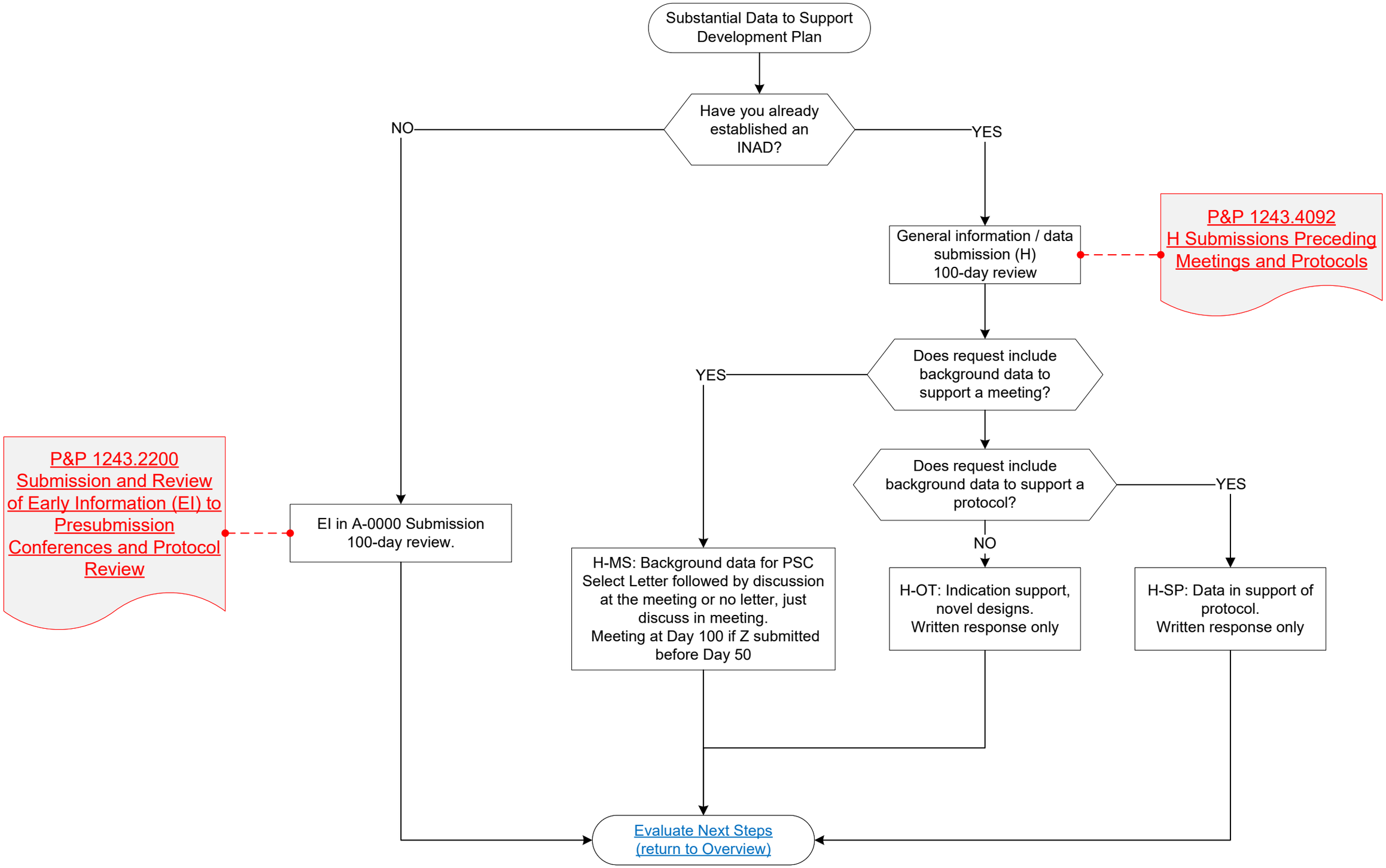
P&P 1243.2200 Submission and Review of Early Information (EI) to Presubmission Conferences and Protocol Review

If you have EI, consider submitting it now,
as it may decrease the time to approval.

Timeline: 100-day review

Return to Overview


Quick Question
Do you need an official response from ONAPE as part of the INAD file?
YES
NO
Does this require time and deliberation for ONAPE to adequately address?
NO
YES
Informal Communication (Z)
Do you know your ONAPE contact?
YES
NO
ONAPE determines that the question(s) can be answered by informal communication?
NO
YES
Email known contact at ONAPE
Email ASKONAPEPM@fda.hhs.gov.
Submission transitioned to an Other ONAPE (OO) Meeting
Target response time: 14 days
Evaluate Next Steps (return to Overview)
P&P 1243.3013 Receiving and Responding to Informal Communication Requests through eSubmitter
You may use this process for questions that require time and deliberation for ONAPE to adequately address, but for which a meeting with ONAPE may not be needed, e.g., scientific clarifications, policy questions, and formatting issues. The process is ideal for questions that fall between those warranting a brief clarifying e-mail and a formal meeting.


Substantial Data to Support Development Plan
Have you already established an INAD?
NO
YES
General information / data submission (H) 100-day review
P&P 1243.4092 H Submissions Preceding Meetings and Protocols
Does request include background data to support a meeting?
YES
Does request include background data to support a protocol?
YES
NO
P&P 1243.2200 Submission and Review of Early Information (EI) to Presubmission Conferences and Protocol Review
EI in A-0000 Submission 100-day review.
H-MS: Background data for PSC Select Letter followed by discussion at the meeting or no letter, just discuss in meeting. Meeting at Day 100 if Z submitted before Day 50
H-OT: Indication support, novel designs. Written response only
H-SP: Data in support of protocol. Written response only
Evaluate Next Steps (return to Overview)

P&P 1243.3024 Scheduling and Holding Meetings With Outside Parties

Meeting to Discuss Z-OM

P&P 1243.3025 Preparing Meeting Documentation

Do you have a substantial amount of data to discuss at the meeting?

YES → Utilize Substantial data review followed by meeting (H-MS)

NO

PSC or non-PSC?

Non-PSC

Meeting
Z-OO

Submit Z submission
Information for non-PSC

Meeting usually held within 60 days

MOC provided within 45 days

PSC

Virtual

Straightforward questions,
Clear path forward

ERL with Optional Virtual meeting
Z-PS

Submit Z submission w/ ERL
List of straightforward questions about specific topics.

Optional meeting scheduled to be held within 60 days.
Receive ERL (not binding) six days before meeting date.

3 days to decide:
Clarification to ERL needed?

NO

Meeting cancelled: ERL serves as record.

YES

Meeting held:
Binding PSC agreements
Clarifying dialog only
30-day MOC timeline

Complex development plans
that require substantial discussion

In-person

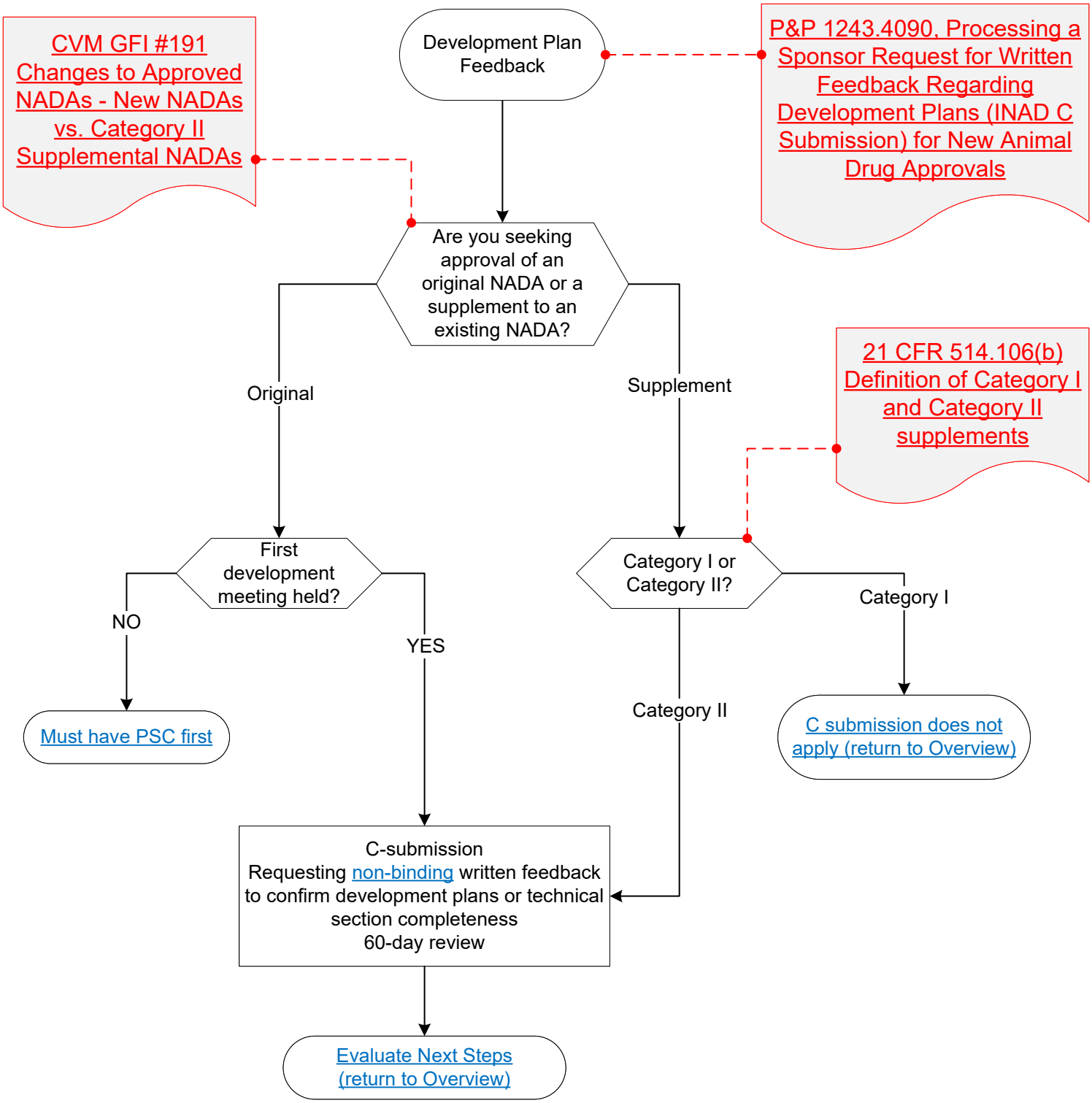
Meeting
Z-PS

Submit Z submission
Complete detailed agenda

Meeting scheduled to be held within 60 days.

Binding PSC agreements
Detailed dialog
45-day MOC timeline

Evaluate Next Steps
(return to Overview)


CVM GFI #191 Changes to Approved NADAs - New NADAs vs. Category II Supplemental NADAs
Development Plan Feedback
P&P 1243.4090, Processing a Sponsor Request for Written Feedback Regarding Development Plans (INAD C Submission) for New Animal Drug Approvals
Are you seeking approval of an original NADA or a supplement to an existing NADA?
Original
Supplement
21 CFR 514.106(b) Definition of Category I and Category II supplements
First development meeting held?
NO
YES
Must have PSC first
Category I or Category II?
Category I
C submission does not apply (return to Overview)
Category II
C-submission
Requesting non-binding written feedback to confirm development plans or technical section completeness
60-day review
Evaluate Next Steps (return to Overview)

Per 21 CFR 514.5(g):

An agreement made under a presubmission conference requested under section 512(b)(3) of the act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if:

(1) FDA and the potential applicant mutually agree to modify, in part or in whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

Feedback provided in the acknowledgment letter of an INAD C or an ERL is considered non-binding, as binding agreements can only be made during a PSC. CVM's feedback is predicated on the accuracy and completeness of the information included in the C or Z submission. CVM's feedback may be modified in the future if substantiated scientific requirements essential to the determination of safety or effectiveness arise after the review of the C or Z submission, including new scientific issues/ information.

Return to Overview Page

Per 21 CFR 514.5(g):

An agreement made under a presubmission conference requested under section 512(b)(3) of the act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if:

(1) FDA and the potential applicant mutually agree to modify, in part or in whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

Feedback provided in the acknowledgment letter of an INAD C or an ERL is considered non-binding, as binding agreements can only be made during a PSC. CVM's feedback is predicated on the accuracy and completeness of the information included in the C or Z submission. CVM's feedback may be modified in the future if substantiated scientific requirements essential to the determination of safety or effectiveness arise after the review of the C or Z submission, including new scientific issues/ information.

Return to Meetings Page

Per 21 CFR 514.5(g):

An agreement made under a presubmission conference requested under section 512(b)(3) of the act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if:

(1) FDA and the potential applicant mutually agree to modify, in part or in whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

Feedback provided in the acknowledgment letter of an INAD C or an ERL is considered non-binding, as binding agreements can only be made during a PSC. CVM's feedback is predicated on the accuracy and completeness of the information included in the C or Z submission. CVM's feedback may be modified in the future if substantiated scientific requirements essential to the determination of safety or effectiveness arise after the review of the C or Z submission, including new scientific issues/ information.

Return to INAD C Page

Communication Tool Selection Flowchart – Text Version

Overview This flowchart helps sponsors determine which communication tool to use when interacting with ONAPE (Office of New Animal Drug Evaluation) at FDA's Center for Veterinary Medicine (CVM).

Step 1: Starting Point Do you have a previously agreed-upon development plan, or is this a B1 supplement?

- YES → Go to Step 2 (Meeting to Discuss).
- NO → Go to Step 3.

Step 2: Do you want the option for written communication only?

- YES → See Written Communication options below.
- NO → Do you want to meet in person? See Meeting options below.

Step 3: Are you ready for agreement on your product development plan for one or more technical sections?

- YES → Go to Meeting to Discuss.
- NO → Do you need additional feedback?
    - NO → None (no action needed).
    - YES → What type of engagement?
        - Substantial data to support development plan → See Substantial Data path.
        - Quick question → See Quick Question path.

Quick Question Path Do you know your ONAPE contact?

- YES → Email your known contact at ONAPE.
- NO → Email ASKONAPEPM@fda.hhs.gov.

Do you need an official response from ONAPE as part of the INAD file?

- YES → Informal Communication (Z). Target response time: 14 days.
    - Reference: P&P 1243.3013 – Receiving and Responding to Informal Communication Requests through eSubmitter.

        - You may use this process for questions that require time and deliberation for ONAPE to adequately address, but for which a meeting may not be needed (e.g., scientific clarifications, policy questions, formatting issues).
        - Does this require time and deliberation for ONAPE to address?
            - YES → Does ONAPE determine the question can be answered by informal communication?
                - YES → Informal Communication (Z).
                - NO → Submission transitioned to an Other ONAPE (OO) Meeting.
            - NO → Evaluate Next Steps (return to Overview).
- NO → Evaluate Next Steps (return to Overview).

Substantial Data to Support Development Plan Path Have you already established an INAD?

- YES → General Information / Data Submission (H). 100-day review.
    - Does the request include background data to support a meeting?
        - YES → H-MS: Background data for PSC. Meeting at Day 100 if Z submitted before Day 50.
        - NO → Does the request include background data to support a protocol?
            - YES → H-SP: Data in support of protocol. Written response only.
            - NO → H-OT: Indication support, novel designs. Written response only.
    - Reference: P&P 1243.2200 – Submission and Review of Early Information (EI) to Presubmission Conferences and Protocol Review.
    - Reference: P&P 1243.4092 – H Submissions Preceding Meetings and Protocols.
- NO → EI in A-0000 Submission. 100-day review.
    - A-0000 Required Information: Sponsor info, Drug ID, Target Species, Dosage, Indication.

- Reference: P&P 1243.4000 – Processing a Request to Open an Investigational (INAD) or Generic Investigational New Animal Drug (JINAD) File.

Meeting to Discuss Do you want written feedback only?

- YES → Do you need binding agreement?
    - YES → Presubmission Conference (PS).
    - NO → Early Response Letter w/ optional Virtual Presubmission Conference (PS).
- NO → Do you need binding agreement?
    - YES → A-0000 (w/EI) or H.
    - NO → A-0000 (no EI) or Other ONAPE Meeting (OO).

Presubmission Conference (PSC) Details PSC or non-PSC?

- PSC → Do you have a substantial amount of data to discuss at the meeting?
    - YES → Utilize Substantial data review followed by meeting (H-MS). Submit Z submission. Meeting scheduled within 60 days.
    - NO → Virtual or In-Person?
        - Virtual (Z-PS) → Submit Z submission w/ ERL. List of straightforward questions. 3 days to decide: Is clarification to ERL needed?
            - YES → Meeting held. Binding PSC agreements. Clarifying dialog only. 30-day MOC timeline.
            - NO → Meeting cancelled. ERL serves as record.
        - In-Person (PSC) → Submit Z submission. Complete detailed agenda. Binding PSC agreements. Detailed dialog. 45-day MOC timeline.
    - Reference: P&P 1243.3024 – Scheduling and Holding Meetings With Outside Parties.
    - Reference: P&P 1243.3025 – Preparing Meeting Documentation.
- Non-PSC → Other ONAPE Meeting (OO). Meeting usually held within 60 days. MOC provided within 45 days. Submit Z submission (Z-OO).

Development Plan Feedback Path Are you seeking approval of an original NADA or a supplement to an existing NADA?

- Original → First development meeting held?
    - YES → Category I or Category II?
        - Category I → C-submission: Non-binding written feedback to confirm development plans or technical section completeness. 60-day review.
        - Category II → Must have PSC first.
    - NO → Must have PSC first.
- Supplement → C submission does not apply (return to Overview).
    - Reference: P&P 1243.4090 – Processing a Sponsor Request for Written Feedback Regarding Development Plans (INAD C Submission) for New Animal Drug Approvals.
    - Reference: 21 CFR 514.106(b) – Definition of Category I and Category II supplements.
    - Reference: CVM GFI #191 – Changes to Approved NADAs – New NADAs vs. Category II Supplemental NADAs.

Binding Agreement Note Per 21 CFR 514.5(g): An agreement made under a presubmission conference requested under section 512(b)(3) of the act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if: (1) FDA and the potential applicant mutually agree to modify the agreement and such modification is documented; or (2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

Feedback provided in the acknowledgment letter of an INAD C or an ERL is considered non-binding, as binding agreements can only be made during a PSC. CVM's feedback is predicated on the accuracy and completeness of the information included in the C or Z submission. CVM's feedback may be modified in the future if substantiated scientific requirements essential to the determination of safety or effectiveness arise after the review of the C or Z submission, including new scientific issues/information.