SOPP 8215: Management of Regenerative Medicine Advanced Therapy Products: Request for Designation, Sponsor Interactions, and Status Assessment

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Table of Contents

I. Purpose 1
II. Scope 2
III. Background 2
IV. Definitions 3
V. Policy 3
VI. Responsibilities 6
VII. Procedures 8
A. Request for Regenerative Medicine Advanced Therapy (RMAT) Designation 8
B. Request for Withdrawal 9
C. Initial Comprehensive Multidisciplinary Meeting with Sponsor 10
D. CBER Periodic Summary Review of RMAT Designated Product Development Programs for Maintaining RMAT Designation 12
E. Intent to Rescind an RMAT Designation 13
F. Sponsor's Response to Intent to Rescind RMAT Designation letter 14
G. Rescinding RMAT Designation 14
VIII. Appendix 15
IX. References 15
X. History 16

I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff to process requests for regenerative medicine advanced therapy (RMAT) designation for biological products, in accordance with Section 506(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to expedite the development and review of RMAT-designated products until a marketing application has been submitted.

II. Scope

A. This SOPP includes the procedures for:

- Review of a request for RMAT designation submitted to an original Investigational New Drug Application (IND) or IND amendment;
- Review of requests to withdraw an RMAT designation or designation request;
- RMAT related CBER-sponsor meetings and other communications;
- CBER periodic summary reviews for the RMAT designation; and
- Procedures related to rescinding the RMAT designation.

B. This SOPP does not cover general administrative procedures for INDs.

C. This SOPP does not address the specific content of scientific reviews.

D. This SOPP does not cover fast track, breakthrough, accelerated approval or priority review designations for RMAT-designated products.

E. This SOPP does not cover the review of Biologics License Applications (BLAs) submitted for RMAT-designated products.

III. Background

A. The field of regenerative medicine encompasses a wide scope of innovative products including cell therapies, therapeutic tissue engineering products, human cell and tissue products regulated as biological products, certain gene therapies, and certain combination products using such therapies. Examples include genetically modified cellular therapies, such as chimeric antigen receptor T-cells (CAR T cells) and cultured human tissues grown on scaffolds for subsequent use. These products hold potential in addressing serious unmet medical needs.

B. Recognizing the importance of this field, Congress included several provisions related to regenerative medicine in the 21st Century Cures Act, signed into law on December 13, 2016. Building on the FDA's existing expedited programs available to regenerative medicine products, one of these provisions established a new program to facilitate the efficient development and review of these products, RMAT Designation.

C. Section 506(g) of the FD&C Act, as amended by Section 3033 of the 21st Century Cures Act, states that a drug is eligible for RMAT designation if:

- The drug is a regenerative medicine therapy, which is defined in Section 506(g)(8) of the FD&C Act as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination product using any such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations.

    - FDA's guidance document[1] clarifies important aspects of the RMAT designation established by the 21st Century Cures Act. In particular, the guidance expressly includes "gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues" and "xenogeneic cell products" in FDA's interpretation of a "regenerative medicine therapy" that may be eligible for RMAT designation.

- The drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and,

- Preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

IV. Definitions

Not Applicable

V. Policy

A. Sponsors may request RMAT designation with submission of an IND or in an amendment to an existing IND and, ideally, no later than the end-of-phase 2 meeting. RMAT designation cannot be granted in the pre-IND phase but may be discussed.

B. RMAT designation, fast track designation, and breakthrough therapy designation are distinct designation programs with different programmatic requirements. Sponsors may apply for and receive more than one designation for a given product, but sponsors must apply for each designation separately. In addition, requests for designation of different indications must be submitted separately.

C. CBER will notify the sponsor within 60 calendar days after receipt of the RMAT designation request as to whether the regenerative medicine therapy (RMT) has received the RMAT designation. If CBER determines that the RMT does not meet the criteria for RMAT designation, CBER will include a written description of the rationale for the decision.

[1] Guidance for Industry: Expedited Programs for Regenerative Medicines for Serious Conditions, available at Expedited Programs for Regenerative Medicine Therapies for Serious Conditions | FDA

D. If a request was denied because the preliminary clinical evidence does not indicate that the drug has the potential to address unmet medical needs for such disease or condition and a sponsor submits new clinical data, then that request will be considered a new designation request.

E. If a sponsor disagrees with CBER's rationale for denying the RMAT designation, then the sponsor may ask the division to reconsider based on the rationale stated in the denial letter. Such requests, without submission of new clinical data, generally will be reviewed within 60 days. The sponsor will be notified in writing of CBER's decision.

F. CBER will not grant requests for RMAT designation submitted to INDs that are inactive. However, if there is a request for IND reactivation that also includes a designation request, the designation request review should proceed.

G. If the IND is on clinical hold or partial clinical hold at the time the RMAT designation request is received or if the request was received with the original IND submission and it is placed on clinical hold during the initial 30 day review period, the circumstances of the hold/partial hold will be considered to determine how they may affect the RMAT designation, e.g., whether the hold issues preclude a determination of whether the product has the potential to address an unmet medical need.

H. Sponsors of RMAT-designated products are eligible for earlier, expedited, and more frequent interactions with the FDA, similar to those interactions available to sponsors of breakthrough-designated therapies.

I. The regulatory project manager (RPM), review team, their immediate supervisors (Branch Chiefs), and senior leadership will follow the processes and procedures outlined in the *Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants for PDUFA Products* and *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* when scheduling and conducting meetings for RMAT-designated products.

J. The review team and supervisors will follow CBER's Managed Review Process when reviewing IND submissions for RMAT-designated products. These principles and practices include adhering to review timelines for original INDs, IND amendments, official correspondence, meetings, documentation, and supervisory concurrence, when necessary, of written reviews.

K. The review team and supervisors will follow the principles set forth in the *Guidance for Industry and Review Staff: Good Review Practice: Best*

Practices for Communication Between IND Sponsors and FDA During Drug Development.

L. IND amendments related to the development of RMAT-designated products, e.g., clinical trial, chemistry, manufacturing, and controls (CMC), or pharmacology/toxicology information, will receive expedited review and, when applicable, a prompt response to the sponsor. The review timeline for these amendments will generally be 60 days, unless a different timeline is indicated by statute, regulation (e.g., response to clinical hold) or user fee agreements.

M. Periodic reviews will be conducted at least annually to assess the continued adequacy of the proposed overall product development plan to facilitate an expedited development program.

N. If RMAT designation has been granted, but later in development the product no longer meets the qualifying criteria, CBER may rescind the designation. CBER will notify the sponsor in writing of their intent to rescind the RMAT designation. The Intent to Rescind RMAT Designation letter will include the criteria for making such a determination and provide the sponsor with an opportunity to submit additional data and justification to support the continuing RMAT designation and/or to request a meeting with CBER to discuss the RMAT designation for the product.

1. If the sponsor does not submit additional justification or supportive data or request a meeting within 60 days of receipt of the Intent to Rescind RMAT Designation letter, CBER may rescind the RMAT designation.

2. If after review of additional information and meeting with the sponsor, if applicable, CBER decides to rescind the RMAT designation, CBER will notify the sponsor in writing and will provide the rationale for this decision in the Rescind RMAT Designation letter. The rescinding of an RMAT designation does not necessarily mean that the product is not promising or that the product may not receive marketing approval. It means that the criteria for RMAT designation are no longer met.

O. Marketing applications for RMAT-designated products may be eligible for priority review, accelerated approval, and/or rolling review as described in the *Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics*. As stated in Appendix A of the guidance, rolling review should be discussed at the pre-BLA meeting (or sooner). Generally, a complete portion (i.e., an eCTD module), such as the entire CMC section, toxicology section or clinical section should be submitted, unless submission of an incomplete module was agreed upon. If rolling review is agreed upon, ideally, all portions of the application should be submitted no more than one year after the initial submission. Any review of portions already submitted may be suspended because our ability to conduct a meaningful review may be inhibited without

the missing information. Efficacy supplements for products and indications with RMAT designation are also eligible for rolling review.

VI. Responsibilities

A. Regulatory Project Manager (RPM)

1. Serves as the primary point of contact with the sponsor.

2. Stays up to date on the status of the RMAT development program, including planned and on-going clinical trials, product development plans, discipline-specific information requests, meetings, teleconferences with the sponsor, along with timelines, milestones, and due dates.

3. Ensures the review team is kept up to date on all aspects, except scientific issues, of the product development program (PDP).

4. Facilitates all review team and CBER-sponsor meetings (or designates a qualified staff member to facilitate, if unable to attend), and works to ensure that the review team and CBER-sponsor meetings for RMAT-designated products are prioritized on the calendar.

5. Communicates with the appropriate point of contact (e.g., RPMs) in other CBER offices and FDA Centers to exchange information, coordinate efforts, and request consults when the review team requires additional scientific expertise.

B. Regulatory Information Specialist (RIS)

1. Schedules internal and sponsor meetings.

C. Quality Assurance Specialist (QAS)

1. Organizes and plans the Periodic Summary Review (PSR) meetings for RMAT-designated INDs.

2. Facilitates discussion and leads recurring PSR meetings.

3. Maintains the Summary Review document and facilitates its updating by the review team before recurring meetings.

D. Review Team Member

1. Reviews RMAT-related submissions as assigned.

2. Meets regularly with their supervisor to provide updates on the status and progress of the RMAT development program.

3. Identifies issues with the RMAT development program, proposes potential solutions when appropriate, and communicates issues to their supervisor and the RPM as soon as possible.

E. Office of Regulatory Operations, Division of Informatics, Regulatory Information Branch (RIB)

1. Performs initial characterization of original INDs and IND amendments.

2. Provides performance reports related to RMAT.

F. Discipline Branch Chief

1. Meets regularly with the discipline review team member to stay up to date on the status and progress of the RMAT development program.

2. Ensures the quality and consistency of discipline reviews of RMAT designation requests.

3. Keeps the discipline Division Director up to date regarding the status of the RMAT development program.

4. Attends sponsor meetings as resources permit.

G. Discipline Division Director

1. Meets regularly with the discipline-specific Branch Chief to keep appraised of the status of the RMAT development program.

2. Keeps their Office Director up to date on the status of RMAT development programs within the division.

3. Resolves differences in scientific opinions between disciplines, as needed.

4. Attends sponsor meetings as resources permit.

H. Office of Clinical Evaluation (OCE) Director/Deputy, CMC Office Director/Deputy, ORMRR Office Director, and OTP IOD Leadership

1. Stays informed of the status of RMAT development programs within the Office through the Division Directors.

2. Addresses specific issues or policy questions brought to their attention through the discipline or division management chain.

3. Consults with CBER's Office of Regulatory Operations (ORO) Director, the Center Director, the Director of the Office of Therapeutic Products (OTP),

and appropriate groups as necessary regarding RMAT development issues.

VII. Procedures

A. Request for Regenerative Medicine Advanced Therapy (RMAT) Designation

1. Check to ensure that the request is not submitted to a pre-IND file or to an inactive IND. **[RPM]**

a. If submitted to a pre-IND file, inform sponsor via telecon or secure email (if established with the requester) that a request for RMAT-designation cannot be made before the submission of an IND.

b. If the IND is inactive, deny the designation request using the deny RMAT designation letter template. However, if a request for IND reactivation is also included in the amendment, the designation request review should proceed.

2. Verify that the designation request is specific to a single indication of a single product and is only for RMAT designation.

a. If request is for multiple indications, inform sponsor that each indication requires a separate designation request.

b. If sponsor has also requested another type of designation (breakthrough therapy, fast track), inform sponsor that each program requires a separate designation request.

c. Document communication in the appropriate regulatory system and ensure the amendment characterization reflects only the single request. **[RPM]**

3. Verify that the request has been characterized accurately in the appropriate system, update if necessary, and inform RIB of any changes that have been made. **[RPM]**

4. Route the request to the IND review team, alert relevant office leadership that an RMAT designation request has been received and provide the review timeline. Note: Ensure a statistical reviewer also has been assigned. **[RPM]**

5. Send acknowledgement of receipt of RMAT designation request letter to sponsor no later than 14 calendar days after CBER receipt and upload it into the administrative file through CBER Connect. **[RPM]**

6. Schedule Leadership Submission Briefing. **[RPM]**

7. Confirm with clinical team if an Oncology Center of Excellence presentation is needed (only for oncology or malignant hematology indications). **[RPM]**

    a. If so, request an OCE Medical Oncology Review (MOR) team. After the review team is assigned, schedule an OCE presentation.

    b. If the decision after Leadership Submission Briefing is to deny the request, cancel the OCE presentation.

8. Review request for designation using *T843.02: CBER Regenerative Medicine Advanced Therapy (RMAT) Designation Determination Review* and make decision based on criteria in the *Guidance for Industry: Expedited Programs for Regenerative Medicine Therapies for Serious Conditions*. **[Review Team]**

    a. Determine if consults are needed. If inter-center, follow *SOPP 8001.5: Inter-Center Consultative Review Process.*

    b. Attend Leadership Submission Briefing.

    c. Hold meeting with Oncology Center of Excellence for oncology or malignant hematology indication.

    d. Ensure the review memo is uploaded through CBER Connect into the administrative file.

9. Send letter to sponsor denying or granting designation within 60 days of receipt of request and upload communication through CBER Connect. **[RPM]**

    a. If RMAT designation is granted, provide guidance to the sponsor describing content of initial comprehensive meeting as described in Appendix A.

B. Request for Withdrawal

1. Receive request for withdrawal of RMAT-designation or RMAT-designation request. **[DCC]**

2. Forward the request to the RPM and RIB. **[DCC, ESC]**

3. Characterize the request in the appropriate system. **[RIB]**

4. Verify that the request has been characterized accurately, and update/correct as needed in the appropriate regulatory system. **[RPM]**

5. Route the request to the IND review team. **[RPM]**

6. Alert IND review team and relevant office leadership that a request for withdrawal of RMAT designation or RMAT designation request has been received. **[RPM]**

7. Acknowledge request for withdrawal of RMAT designation or RMAT designation request by issuing *Withdrawal – Regenerative Medicine Advanced Therapy Request* letter no later than 14 calendar days after CBER receipt. **[RPM]**

8. Enter the communication into the appropriate regulatory system and upload it through CBER Connect into the administrative file. **[RPM]**

C. Initial Comprehensive Multidisciplinary Meeting with Sponsor

1. Receive and route sponsor request for initial comprehensive multidisciplinary meeting to all review team members. **[RPM]**

   a. The sponsor should be encouraged to hold the meeting as soon as possible; however, the timing of the meeting may depend on where the sponsor is in their product development program (PDP) when the RMAT designation is granted.

2. Schedule pre-meeting and sponsor meeting. **[RPM]**

   a. The initial comprehensive meeting may be an IND milestone meeting, e.g., End of Phase (EOP) 2 meeting.

   b. A combined milestone/initial comprehensive multidisciplinary meeting should use the procedures and processes for the milestone meeting. The attendees for a combined meeting must include all required participants for the initial comprehensive meeting.

3. Receive and route meeting package. **[RPM]**

   The meeting package should include an overall high-level coordinated PDP including, at a minimum:

   a. Regulatory issues, such as expanded access plans, and plans for submission of a proprietary name request;

b. Current and planned clinical trials and data analysis, including early plans to mitigate or minimize risk, and the proposed pediatric development plan;

c. Nonclinical pharmacology, pharmacokinetics, and toxicology information; and

d. CMC and facility information.

4. Attend the pre-meeting for the initial comprehensive multidisciplinary meeting with the sponsor. **[RPM, Review Team, Branch Chiefs, Division Directors]**

5. Attend initial comprehensive multidisciplinary sponsor meeting. **[RPM, Review Team, Branch Chiefs, Division Directors]**

a. Provide guidance and advice specific to the product and reach agreement on a planned development program (PDP).

b. Discussion topics depend on the therapeutic area, development phase, and specific development program issues of the proposed product and indication, and could include:

i. General and/or regulatory plans;

ii. Planned clinical trials and endpoints;

iii. Plans for expediting the manufacturing development strategy;

iv. Studies that potentially could be completed after approval.

Refer to Appendix A: Discussion Topics for the Initial Comprehensive Multidisciplinary RMAT Meeting for a detailed list of possible discussion topics.

c. Discuss a communication plan with the sponsor. The plan should include the proposed timing and frequency of future meetings and teleconferences, information requests, and other submissions to the IND related to the RMAT PDP. **[RPM, Review Team, Branch Chiefs, Division Directors]**

i. Teleconferences and secure emails, as appropriate, may serve as tools for focused discussions, rapid information exchange, and issue resolution on procedural, regulatory, or scientific matters regarding the nonclinical and clinical development of the RMAT-designated product.

ii. CBER will communicate with the sponsor outside of critical milestone meetings to provide intensive guidance on efficient product development. These communications will likely be discipline-focused to discuss specific development program data, milestones, and issues.

iii. IND amendments related to the development of RMAT-designated products will generally be reviewed within 60 days, unless a different timeline is indicated by statute, regulation (e.g., response to clinical hold), or user fee agreements.

iv. CBER will follow the principles set forth in the *Guidance for Industry and Review Staff: Best Practices for Communication between IND Sponsors and FDA during Drug Development.*

6. Document meeting per established procedures (follow *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products*). **[RPM, Review Team]**

D. CBER Periodic Summary Review of RMAT Designated Product Development Programs for Maintaining RMAT Designation

1. Schedule recurring standing Periodic Summary Review (PSR) meetings. **[QAS]**

2. Remind review team before the meeting to update relevant files in the Summary Review Document with any new information pertaining to product development for the RMAT designation. Note: This document is updated before every PSR meeting for the life cycle of the RMAT designated IND. **[QAS]**

3. Meeting discussion will assess the continued adequacy of the proposed overall product development plan to facilitate an expedited development program. **[Review Team, Office and Division Leadership, OTP IOD]**

Meeting discussion items may include but are not limited to the following:

a. Status of product development for each discipline;

b. Upcoming milestone meetings, if applicable;

c. Status of the product development program (PDP) agreed upon during the initial comprehensive meeting (e.g., has any agreed upon clinical trial(s) started);

d. Outstanding information requests (IRs);

e. Key findings and substantive issues and/or major deficiencies identified;

f. Potential impact the substantive issues and/or major deficiencies might have on the PDP and plans for addressing them (e.g., product scale up and/or facility issues); and

g. Whether the PDP continues to meet the criteria for RMAT designation. **[Clinical Reviewer]**

4. Archive the Review Document with updates from each PSR meeting to record the progress of all RMAT designated INDs. **[QAS]**

E. Intent to Rescind an RMAT Designation

1. Determine that the criteria for RMAT designation are no longer met. **[Review Team]**

2. Document rationale/findings using *T 815.03: Intent to Rescind Fast Track, Breakthrough Therapy, or RMAT Designation Memo* and distribute to the RPM and review team. **[Appropriate Discipline Reviewer]**

3. Route memo through immediate supervisor to Division Director for concurrence. **[Appropriate Discipline Reviewer]**

4. Return signed memo to the appropriate Discipline Reviewer, with a cc to the RPM. **[Division Director]**

5. Ensure the review memo is uploaded into the correct administrative file through CBER Connect. **[Discipline Reviewer(s)]**

6. Alert Sub-Office Director that PDP no longer meets criteria for RMAT designation and ensure OD agrees. **[Team, Division Director]**

7. Notify senior management (including OTP Director, ORO Director, and the Deputy Center Director) that the PDP no longer meets the criteria for RMAT designation and Intent to Rescind RMAT Designation letter will be issued to the sponsor. **[RPM]**

8. Draft Intent to Rescind RMAT Designation letter. **[RPM]**

9. Route draft letter to the review team, branch chiefs, and senior management. **[RPM]**

10. Review letter and provide clearance to RPM. **[Review Team, Branch Chiefs, Senior Management]**

11. Finalize letter and circulate for final concurrence and sign-off. **[RPM]**

12. Sign Intent to Rescind RMAT Designation letter. **[Division Director]**

13. Issue letter to sponsor and upload the letter through CBER Connect. **[RPM]**

F. Sponsor's Response to Intent to Rescind RMAT Designation letter

1. Receive response and forward request to the RPM and RIB. **[DCC]**

2. Characterize the request in the appropriate system. **[RIB]**

3. Route amendment to the review team. **[RPM]**

4. Review additional information, data, and/or rationale provided in the sponsor's response. **[Review Team]**

5. If the sponsor's response includes a request for a meeting, schedule the meeting and invite appropriate staff (refer to *SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products* for meeting policies and procedures). **[RPM]**

6. Attend pre-meeting and sponsor meeting. **[Review Team, Branch Chiefs (Discipline Division Director(s))]**

   Discussion topics should include:

   a. The additional information, data, and/or rationale for maintaining RMAT designation provided in the sponsor's response.

   b. Explanation of why the RMAT designation should be maintained or rescinded.

   c. If recommendation is to maintain RMAT designation, plans for a path forward for the development of the product.

5. Make decision to maintain or rescind RMAT designation. **[Review Team, Division Directors, Office Directors, OTP Director, OTP IOD Leadership]**

G. Rescinding RMAT Designation

1. If the sponsor does not submit additional justification or supportive data or request a meeting within 60 days of receipt of the Intent to Rescind RMAT Designation letter, complete *T 815.04: Rescinding Fast Track, Breakthrough Therapy or RMAT Designation Review Memo* and route through Immediate Supervisor to Division Director for sign off. **[Appropriate Discipline Reviewer]**

2. Return signed memo to the appropriate Discipline Reviewer, with a cc to the RPM. **[Division Director]**

3. Notify the entire review team, including immediate supervisors, senior management (e.g., OTP Director, ORO Director, and Deputy Center Director) that a Rescind RMAT Designation letter will be issued to the sponsor. **[RPM]**

4. Draft Rescind RMAT Designation letter. **[RPM]**

5. Route draft letter to the review team, Branch Chiefs, and Senior Management. **[RPM]**

6. Review letter and provide clearance to RPM. **[Review Team, Branch Chiefs, Senior Management]**

7. Finalize letter and circulate for final concurrence and sign-off. **[RPM]**

8. Sign Rescind RMAT Designation letter. **[OCE Director]**

9. Issue the letter to sponsor and upload it through CBER Connect. **[RPM]**

10. Ensure the review memo is uploaded into the administrative file through CBER Connect. **[Appropriate Discipline Reviewer]**

VIII. Appendix

A. Appendix A: Discussion Topics for the Initial Comprehensive Multidisciplinary RMAT Type B Meeting with the Sponsor

IX. References

A. References below are CBER internal:

1. OTP Email templates

2. CBER RMAT Letter templates

3. SOPP 8001.5: Inter-Center Consultative Review Process

4. T 815.03: Intent to Rescind Fast Track, Breakthrough Therapy, or RMAT Designation Memo

5. T 815.04: Rescinding Fast Track, Breakthrough Therapy, or RMAT Designation Review Memo

6. T843.02: Regenerative Medicine Advanced Therapy (RMAT) Designation Determination Review

B. References below may be found on the Internet:

1. 21st Century Cures Act

2. Draft Guidance for Industry: Expedited Programs for Regenerative Medicine Therapies for Serious Conditions

3. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics

4. Guidance for Industry: Evaluation of Devices Used with Regenerative Medicine Advanced Therapies

5. Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products

6. Guidance for Industry and Review Staff: Good Review Practice: Best Practices for Communication Between IND Sponsors and FDA During Drug Development

7. SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
M. Monser	Sonday Kelly, MS, RAC, PMP Director, DROP/ORO	March 12, 2026	3	Updated policy regarding clinical holds and impact on RMAT designation determination, Updated procedures to ensure documentation is complete. Updated responsibilities for supervisors to attend

Written/ Revised	Approved By	Approval Date	Version Number	Comment
				meetings as available.
M. Monser	Martha Monser, RRDL RABOB/DROP/ ORO	January 8, 2026	2	Updated procedures to ensure documentation is complete. Updated responsibilities for supervisors to attend meetings as available. Replaced “ADRM” with “ORO Director”
M. Monser	Sonday Kelly, MS, RAC, PMP Director, DROP/ORO	September 14, 2023	1	First Issuance

SOPP 8215 Appendix A: Discussion Topics for the Initial Comprehensive Multidisciplinary RMAT Type B Meeting with the Sponsor

Note: The specific topics for discussion will depend on the product, therapeutic area, proposed indication, development phase, and specific development program issues. As such, this list is not intended to be inclusive of all issues that are important to your product but serves as a general guide.

The communication plan between the sponsor and the review team must be discussed and documented in the meeting summary using *T820.06: Meeting Summary Template.*

General Regulatory:

- Brief Regulatory history, including the following:
    - Orphan Drug Designation, Fast Track, Breakthrough Therapy Designation, Regenerative Medicine Advanced Therapy Designation
    - Foreign regulatory history: Where/when approved and for what indications, pending applications with foreign regulators, risk management plans in foreign countries
    - Key Agreements Reached/FDA Advice in previous FDA Interactions
    - Special Protocol Assessment: any agreements/disagreements regarding primary endpoints, secondary endpoints, statistical analysis plan
    - Other pertinent meetings/communications with FDA, marking agreements/disagreements with the Agency
- Pediatric Study Plan
- If a combination product, a plan for the development of each constituent part and of a single-entity product (combined), if applicable
- If the use of your product will require a specific diagnostic test, a co-development plan for the in vitro companion diagnostic device with the Center for Devices and Radiological Health (CDRH)
- Development Plan Milestones
    - Milestones by discipline (CMC, preclinical, clinical)
    - Anticipated PDUFA milestone meetings with FDA-proposed timeframe and format
    - Data or Protocol IND amendments
    - Planned target date for BLA submission
    - Gantt chart of your development program that includes target IND and product development milestones and communications you might request with FDA

Product/CMC:

- Donor eligibility
- Source material and ancillary material controls
- Drug Substance
    - Characterization, critical quality attributes, critical process parameters/ process controls
- Drug Product

    - Dosage form
    - Critical quality attributes, critical process parameters, lot release specifications including potency
    - Administration and delivery system
    - Shelf life and stability studies
- Container/closure
- Plans for extractable and leachable evaluation
- Proposed commercial process & scale-up
- Proposed manufacturing changes and comparability studies, if applicable
- Proposed facility changes, scale out, scale up, and comparability studies, if applicable
- Proposed process and method validation studies
- Quality agreements with contract manufacturing and testing organizations, if applicable

Nonclinical:

- Synopsis of completed and ongoing nonclinical studies. For any planned studies: the rationale for each study, a detailed study protocol, and the timelines for study initiation and submission of the complete study report.
- Developmental and reproductive toxicity (DART) study protocols, as appropriate, with supporting data for each study design.

Clinical:

- General clinical development plan
- Specific indication that studies are intended to support
- Other clinical indications in development for this product
- Trials you are currently conducting to support each indication
- Future trials you plan to conduct to support each indication
- For each trial (current or future), please include the following summary:
    - Overall trial design
    - The population(s) to be studied and for whom the product is intended to be marketed
    - Primary and Secondary Efficacy Endpoints.
        - If you select a surrogate endpoint as the primary endpoint for one or more phase 3 trials in your program, please provide a scientific justification that your chosen surrogate endpoint is reasonably likely to predict the intended clinical benefit
    - Statistical analysis plans
    - Safety database
    - Expected initiation and completion dates
- Indicate the number of sites for the studies intended to provide primary evidence of effectiveness. Indicate if you plan to include U.S. and non-U.S. sites.