OBMEA Monitoring committee  
TEMPLATE FOR TERMS OF REFERENCE (ToR)

*[This template provides an outline terms of reference for a “Monitoring Committee” of an Outcomes-Based Managed Entry Agreement of a rare disease treatment. It should be adapted to suit the healthcare system and this text deleted.]*

**REMIT OF MONITORING COMMITTEE**

The Monitoring Committee is responsible for ensuring the Outcomes-Based Managed Entry Agreement (OBMEA) of rare disease treatment (RDT) in reimbursed indication is implemented in line with the arrangements agreed. The Monitoring Committee oversees the operation of the OBMEA and provides guidance on issues that arise in clinical practice.

This document describes the composition of the OBMEA Monitoring Committee (the “Committee”) and its functions including proposed membership, responsibilities of the members and meeting arrangements.

**BACKGROUND TO THE OBMEA**

*Summarize decision about the value of the RDT and the plans for the OBMEA referring to original HTA/appraisal report, published OBMEA documents.*

**PURPOSE**

*Describe remit of the Committee, consider including*

The Committee shall be responsible for monitoring the implementation of the OBMEA and recommending actions to support its operation. This may include:

1. Monitoring the progress of data collection and analyses as described in the OBMEA and data specification.
2. Ensuring data quality, sufficiency and completeness in line with the requirements of the OBMEA.
3. Reviewing enrolment to and continuation in the OBMEA for each centre, including the number of patients who have discontinued treatment.
4. Agreeing communications (including for patients, clinicians, health service).
5. Considering proposed amendments to the OBMEA (which would be subject to renegotiation by with relevant parties).
6. Reporting annually - providing a status update on the quality and completeness of data with regards to the anticipated re-appraisal date.

The Committee will not:

1. Discuss or negotiate the commercial arrangements
2. Consider any new data with a view to requesting to expand the existing recommendation from the committee.
3. Make other major amendments to the OBMEA
4. Discuss or review individual patient cases.

**MEMBERSHIP**

The membership of the Committee is as follows:

* *Describe membership, this may include HTA/Healthcare Payer staff, clinicians, patient group representatives, Marketing Authorisation Holder*

Decisions will be made via consensus, wherever practicable.

Quoracy is reached when the following members are in attendance:

* *Define essential bodies to be represented and minimum number/percentage of members to be in attendance.*

If a Committee member is unable to attend a meeting, they may send their views to the chair/co-chair to be considered by the committee or send a nominated deputy. The deputy must abide by the rules of the committee, including confidentiality agreements.

**GOVERNANCE**

*Describe governance measures such as:*

* All members of the Committee will be required to complete a Confidentiality Agreement form and Declaration of Interests form before attending any meetings involving discussion of the OBMEA.
* The data reports and information disclosed during the Committee meetings are strictly confidential and must not be shared or discussed with anyone outside of the Committee.
* Any confidential information or patient identifiable data will only be shared with the Committee via *<describe secure system>.*
* Any issues relating to the conduct of the Committee meetings will be escalated to the OBMEA signatories.
* Any breach of the confidentiality agreement could result in the member(s) concerned and their organisation being removed from the Committee.

# RESPONSIBILITIES OF COMMITTEE MEMBERS

*Describe responsibilities of individual members, such as:*

* Attend Committee meetings (every XX months).
* Respect the challenges faced by other members of the committee (particularly clinicians and patients) that may arise in the implementation of the OBMEA and treat all members with sensitivity.
* Ensure the confidentiality of all materials and discussions.
* Provide advice, guidance and agree action points to support the OBMEA implementation.
* Identify the need for, and approve, communications from the Committee.
* Review any proposed amendments to the OBMEA.