

**Improved methods and actionable tools for enhancing HTA**

**Template for Adaptation by HTA Bodies**

Monitoring committee TERMS OF REFERENCE

 FOR An Outcomes-Based Managed Entry Agreement

OF A RARE DISEASE TREATMENT

**March 2021**

*This template provides an outline terms of reference for the “Monitoring Committee” of an Outcomes-Based Managed Entry Agreement (OBMEA) of a rare disease treatment.*

*It uses terminology that comes from the* [*IMPACT HTA Template for OBMEA*](https://www.impact-hta.eu/work-package-10) *and should be adapted to suit the healthcare system.*

*It has been developed from a document used by the National Institute for Health and Care Excellence taking account of knowledge gained in IMPACT HTA Work Package 10 and revised after consultation with the international HTA community.*

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Outcomes-Based Managed Entry Agreement

Monitoring committee TERMS OF REFERENCE

 FOR RARE DISEASE TREATMENT IN REIMBUSED INDICATION

**REMIT OF MONITORING COMMITTEE**

*This is not intended to be a “Data Monitoring Committee” as used in a clinical trial (with responsibility for reviewing accruing data to monitor safety and decide termination according to an interim analysis plan). This RDT has been authorised by regulators and is being used within its licensed indication in clinical practice, so usual safety reporting and local clinical governance measures apply.*

*The purpose of an “OBMEA Monitoring Committee” is to bring together all stakeholders involved in a specific OBMEA to ensure that the real-world data being collected, perhaps from various sources, are of as good quality as they can be. The Committee may also advise on remedial activities to improve data quality, for example if they see issues in a particular centre, or common challenges in obtaining a particular assessment.*

The Monitoring Committee is an advisory committee, 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 implementation of the OBMEA and provides guidance on issues that arise with collecting the data 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 appraisal recommendation or pricing and reimbursement decision about the RDT and why the OBMEA was established. Refer to the HTA or reimbursement report and published OBMEA documents.*

*Refer to details about responsibilities for data collection, management and reporting in the OBMEA, clearly explaining how data will be shared to ensure patient confidentiality.*

**PURPOSE**

*Describe remit of the Committee. Consider including elements such as:*

The Committee will meet quarterly and shall be responsible for monitoring the implementation of the OBMEA and recommending actions to support its operation.

This includes:

1. Monitoring progress of data collection as described in the OBMEA to ensure data quality and completeness, considering issues such as:
	1. patient enrolment
		1. in each centre
		2. checking prescribing figures vs entries in the data collection system
		3. checking recruitment rate and if slower than anticipated exploring reasons for this
	2. checking relevant assessments are being undertaken at appropriate timepoints (even after treatment discontinuation) and data is of good quality and any challenges in clinical practice are resolved (e.g. accessing genetic tests)
	3. agreeing reasonable adjustments for patients unable to perform assessments
	4. agreeing data management rules (e.g. increasing time windows around visits, managing missed visits etc)
2. Reviewing 6-monthly/annual status updates on the sufficiency of the data with regards to the anticipated re-appraisal date and any treatment issues (e.g. as identified in adverse events or reasons for discontinuations)
3. Addressing feedback from clinicians and patients about any issues
4. Discussing proposed amendments to the OBMEA (which would be subject to renegotiation by with signatories).
5. Agreeing information leaflets and project updates to be shared with stakeholders (patients, carers, clinicians, health service).
6. Providing a mid-term report to the appraisal/pricing and reimbursement committee about progress.
7. Presenting a final report on the OBMEA to the HTA/Payer staff and appraisal/pricing and reimbursement committee at the outset of the re-appraisal. This should document any challenges faced in data collection for consideration in the critical assessment and re-appraisal deliberations.

The Committee will not:

1. Discuss or negotiate the commercial/pricing arrangement.
2. Consider any new data with a view to requesting to expand the existing recommendation from the appraisal 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 should include representatives of all the signatories to the OBMEA and may include others such as HTA/Healthcare Payer staff, treating clinicians, patient group representatives, Marketing Authorisation Holder.*
* *Indicate if there are sections of the meeting that can only be attended by certain members due to confidentiality.*

Members are expected to serve for the duration of the OBMEA.

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.

Decisions will be made via consensus, wherever practicable.

**GOVERNANCE**

The HTA body/Expert Centre/Registry Holder will act as Secretariat to the Committee: issuing meeting papers, chairing the meeting, preparing minutes.

*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 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 3 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 (respectful discourse).
* 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.