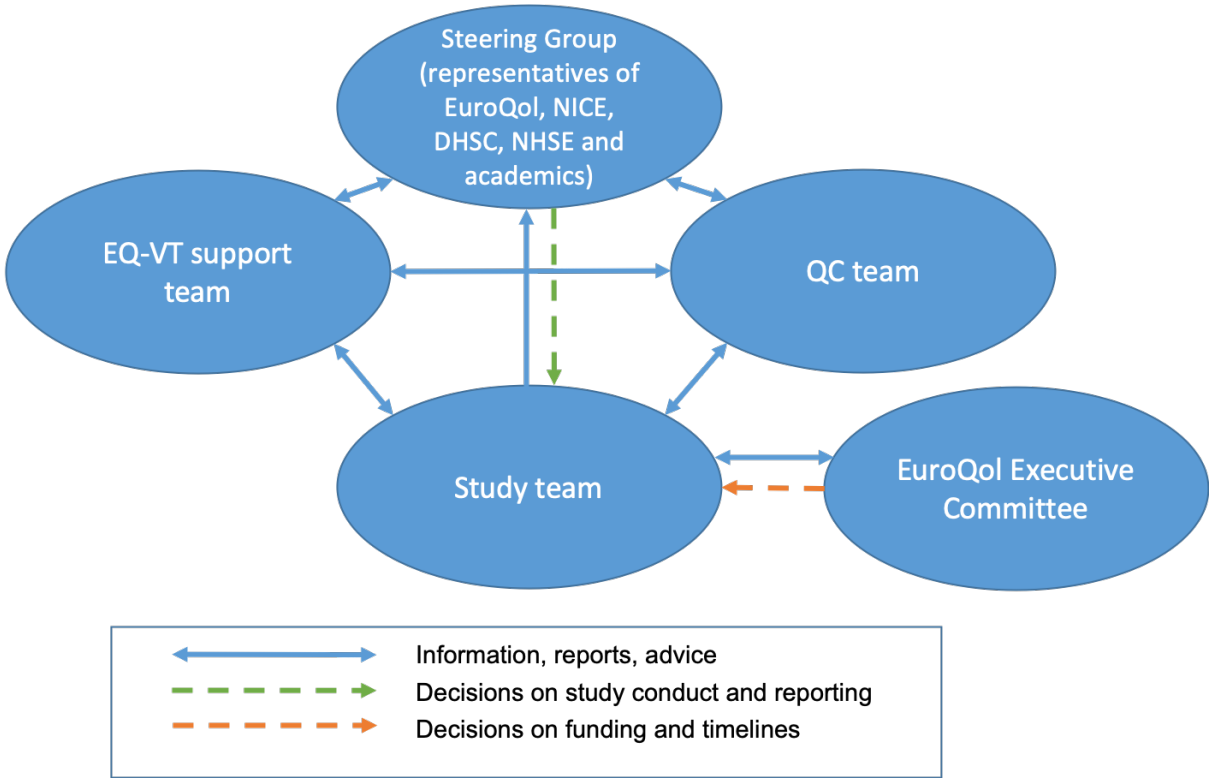
New UK EQ-5D-5L valuation study
Governance arrangements

Version 1.0

Overview

In this document, we delineate the governance arrangements and scope of responsibilities of 5 groups/teams that will be involved in the conduct and oversight of the EQ-5D-5L valuation study in the UK.

Figure 1: relationship between Steering Group, study team, EQ-VT support team, quality-control (QC) team and EuroQol's Executive Committee.



Abbreviations: DHSC, Department of Health and Social Care; NHSE, NHS England and NHS Improvement; NICE, National Institute for Health and Care Excellence.

Reference is also made to the responsibility matrix, which can be found in Appendix 1.

1. The **study team** is responsible for the day-to-day management of the study. This includes writing the study protocol and analysis plan, obtaining ethical approval, collecting the data, modelling the data to produce a value set, writing publications and communications material, and providing materials to an external quality-

control (QC) team at key stages. The study team will be led by a principal investigator (PI), with site investigators responsible for each collaborating centre. Site investigators are responsible for providing qualified staff from the collaborating centre to act as interviewers and/or as modelling experts.

2. The EuroQol **EQ-VT support team** will help the study team in writing the study protocol and analysis plan, and in training the interviewers. They will assist the study team by monitoring the data collection and by providing EQ-VT QC reports on a weekly basis and at the two scheduled interim analyses described in the protocol. The involvement of the EuroQol EQ-VT support team is standard practice for all EQ-VT studies. The QC reports for the scheduled interim analyses will be shared with the Steering Group (see section 3) and the external QC team (see section 4). The EQ-VT support team is headed by Elly Stolk and consists of qualified scientists working from the EuroQol Office in Rotterdam, the Netherlands.

3. The **Steering Group** will provide oversight of the study, including taking responsibility for:

    - Appointing the PI, site investigators and QC team;
    - Approving the protocol and analysis plan developed by the study team after review by the QC team and resolution of any outstanding issues (see section 30);
    - Decisions on a major change to the protocol, if needed (see section 31);
    - Monitoring the progress of the study;
    - Advising the study team on all aspects of the research;
    - Reviewing the reports from the QC team;
    - Approving study reports, publications and communications material (e.g. press releases, website updates and social media content);
    - Liaising with policy-makers regarding implementation of the value set.

4. The **Quality-Control (QC) team** will be independent from the study team, EuroQol's EQ-VT support team and the Steering Group. The QC team is appointed by and accountable to the Steering Group. This team is responsible for reviewing and critically assessing the work of the study team at least during the following four key stages:

    - Reviewing the final protocol and analysis plan;
    - Reviewing the data at the two scheduled interim analyses;
    - Reviewing the complete data set;

- Reviewing the final value set.

The review should be constructive and, where possible, suggest solutions to identified problems. The QC team review should not include the aspects of study design and conduct that were agreed at the outset by the Steering Group (such as the use of EQ-VT 2.1 to gather only time trade-off data). A list of the study design features that were pre-agreed by the Steering Group is in the call for expressions of interest. The scope of work is described fully in the QC contract.

5. If the QC team raises concerns, the study team should consider carefully how to respond and then explain their response to the Steering Group. The Steering Group may ask the study team to provide a written response.

6. The new UK EQ-5D-5L valuation study will be funded by EuroQol Research Foundation. The **EuroQol Executive Committee** will review the final protocol and analysis plan to decide whether funding can be released (see section 30) and will review any protocol changes that require additional funding or extra time.

7. EuroQol will provide reimbursement for members of the Steering Group and QC team.

Steering group

Composition

8. The Steering Group will be chaired by a representative of EuroQol.

9. Initially, the Steering Group will have six members: the Chair, two additional representatives of EuroQol and one representative each of the National Institute for Health and Care Excellence (NICE), Department of Health and Social Care (DHSC) and NHS England/NHS Improvement (NHSE). These six members will appoint two further academic members[1], one expert in collecting health-state valuation data and one expert in modelling valuation data. These eight independent members will not be involved in the study (other than as members of the Steering Group).

10. The processes for appointing the Steering Group and study team are described in sections 21-25.

[1] Note that in this context 'academic' refers to a researcher with expertise in the subject matter; individuals don't necessarily need to be employed by an academic institution.

Conflicts and confidentiality

11. Steering Group members must declare competing interests at the outset of the study and must notify the Chair if these change over the course of the study. Members must also sign a confidentiality agreement in order to maintain the confidentiality of reports that are not yet published.

12. To avoid conflicts of interest, in general, any member of one of the teams involved in the study, such as the study team, EQ-VT support team, QC team, Steering Group or Executive Committee, cannot also be a member of another team involved in the study.

13. The Chair of the Steering Group must be notified of collegial relations between members of different teams, for instance when departmental colleagues would be on the study team and the QC team. The Steering Group will determine if such a situation constitutes a conflict of interest.

Meetings

14. The Steering Group will meet in person at least twice a year. There may be periods when more frequent meetings are necessary, in person or by teleconference, and some issues may need to be dealt with between meetings by phone or by email.

15. Members are expected to prioritise attending Steering Group meetings; sending a delegate is permitted but discouraged. In principle, Steering Group members are expected to stay in post until the UK policy makers have made a final decision of whether to use the new value set.

16. Typically, every Steering Group meeting will have an open part, in which members of the study team and/or the QC team are invited to participate, and a closed part which is attended by Steering Group members only.

17. The PI and a representative of the QC team will be invited to join the open part of all Steering Group meetings. With prior agreement from the Chair, additional members of the study team and QC team may attend the open part of Steering Group meetings. The expertise of the additional attendees should be aligned to the agenda of each meeting.

18. Steering group meetings will be organised by EuroQol, who will circulate minutes after each meeting and retain these on file. Minutes from the closed part of the meeting will be circulated only to Steering Group members and the EuroQol Executive Committee. Minutes from the open part will also be circulated to the study- and QC teams, and relevant EuroQol staff.

19. The Steering Group is quorate when the Chair (or a delegated vice-chair representing EuroQol), one representative of UK policy-makers (NICE, DHSC or NHSE), and 4 more members are present.

20. The Steering Group should aim for decisions based on consensus. If a consensus cannot be reached, the decision will be put to a vote requiring a simple majority. In case of ties, the Chair will have a tie-breaking vote. At the discretion of the Chair a vote may also be taken during a teleconference or via email, in which case the same voting rules will apply.

Table 1: Steering group membership

Organisation	**Name(s)**
EuroQol*	Chair: Bernhard Slaap
EuroQol*	Kristina Secnik Boye
EuroQol*	Jan Busschbach
NICE*	Rosie Lovett
DHSC*	Daniel Law
NHSE*	Danny Palnoch
Academic: expert in collecting valuation data	
Academic: expert in modelling valuation data	
*The initial 6 members will appoint the academic members.	

Process of appointment

21. EuroQol will issue a call for expressions of interest to join the Steering Group, to be the PI, or to be site investigator of a collaborating centre. Estimated timelines are in Table 2.

Process for appointing academic Steering Group members

22. Bernhard Slaap will seek advice from EuroQol's Executive Committee on the applicants. Applications will be shortlisted by Bernhard Slaap and Rosie Lovett. If they disagree, the application will be added to the shortlist. The six initial members of the Steering Group will hold a teleconference to choose their two preferred candidates. Bernhard Slaap and Rosie Lovett will then hold a teleconference with each chosen candidate, to ensure they understand and are comfortable with the aims and limitations of the study.

Table 2: Estimated timelines

Action	Done by	Time allowed (weeks)	Deadline
Issue call for EOI	EuroQol		12 Feb
Researchers prepare applications	Researchers	3	4 Mar
Shortlist academics for Steering Group	BS & RL	0.5	6 Mar
Teleconference to choose academics for Steering Group	Steering group	1	11-13 Mar
Introductory teleconference, sign COI and confidentiality agreements	BS, RL, 2 academics from Steering Group	1	20 Mar
Shortlist PI applications, identify peer reviewers	BS, RL, 2 academics from Steering Group	2	3 April
Peer review of PI applications	Reviewers chosen by steering group	3	24 April
Teleconference to choose PI	Steering group	2	8 May
Face-to-face meeting to choose site investigators	Steering group and PI	2	22 May
In parallel: choose QC team	Steering group		22 May
Contracting	EuroQol	8	17 July
Study starts			

Abbreviations: BS, Bernhard Slaap; EOI, expressions of interest; RL, Rosie Lovett.

Process for appointing the PI

23. Bernhard Slaap will seek advice from EuroQol's Executive Committee on the applicants. Applications will be shortlisted by Bernhard Slaap, Rosie Lovett and the two academic members of the Steering Group. Applications supported by two or more of the shortlisters will be added to the shortlist. Shortlisted applications will be sent out for peer review, with reviewers chosen by the eight members of the Steering Group.

24. The eight members of the Steering Group will hold a teleconference to choose their preferred PI. The Steering Group will choose a selection process that is appropriate to the number and quality of applications. The default selection process will be:

- Each application will be discussed, together with the peer review, and scored by each Steering Group member on a scale from 1 (worst) to 10 (best).
- A mean score will be calculated.
- The applications will be ranked and the final decision based on the rankings, with ties resolved by discussion or, if necessary, a vote.

Process for appointing site investigators

25. Applications will be shortlisted by the PI, Bernhard Slaap, Rosie Lovett and the two academic members of the Steering Group. Applications supported by two or more of the shortlisters will be added to the shortlist. The Steering Group and PI will hold a face-to-face meeting to select the site investigators.

Process for appointing QC team

26. The Steering Group will select the QC team from a shortlist of nominees collated by the Steering Group and EuroQol. The Steering Group will select up to three people based on criteria agreed by the group, such as previous experience of QC, expertise in valuation data, expertise in valuation modelling, etc. Members of the QC team must declare competing interests at the outset of the study and must notify the Chair if these change over the course of the study. Note that members of the QC team may work at separate institutions.

Process for quality assurance of the final value set

27. Policy makers in the UK (such as NICE, DHSC and NHSE) may choose to commission additional quality assurance at the end of the study, to inform their decisions about whether and how to use the new value set. The extent of quality assurance will depend on the quality control reports produced during the study and any concerns about the resulting value set.

Input from other experts

28. The researchers who did the England valuation study published in 2018 (Devlin et al.) have valuable expertise that may be useful to the study team. The study team is encouraged to contact these researchers for informal advice when needed throughout the study. Note that these researchers are also eligible to apply to participate in the study team, QC team or Steering Group.

29. The study team may also find it informative to refer to the quality assurance and expert review of the first English 5L valuation study.

QC Process for key study deliverables (see also Appendix I)

30. The **study protocol and analysis plan** will be written by the study team, with assistance from the EQ-VT support team. These documents will then be reviewed by the QC team and the Steering Group. The QC team will perform a formal QC of the documents. QC findings will be shared with the study team and the Steering Group. After resolution of the QC findings by the study team, the study protocol and analysis plan will be reviewed by EuroQol's Executive Committee to decide whether funding can be released. The Steering Group will sign off on the study protocol and analysis plan once the Executive Committee has approved funding.

31. Two interim analyses are planned during data collection. In these interim analyses interviewer performance, data quality and tentative modelling information will be collated in **interim analysis reports** produced by the study team and the EQ-VT team jointly. The interim reports will be reviewed by the Steering Group. The QC team will perform a QC analysis on the interim reports. Based on the QC analyses the Steering Group will decide whether the study can continue as planned, whether interviewers need to be retrained, or whether the study protocol or analysis plan should be changed. EuroQol's Executive Committee will decide on extra funding or an extension to the timelines, if needed.

32. Once all data has been collected the QC team will produce a **QC report on the complete data set**. The Steering Group will review the complete data set and the QC report before signing off on the final data set for modelling.

33. Once the study team has performed their modelling as specified in the analysis plan they will propose a **final model**. The QC team will then do a QC on the modelling, including the proposed final model. The Steering will sign off on the final model.

Authors

From NICE: Rosie Lovett, Jacoline Bouvy, Nick Crabb, Alan Lamb

From EuroQol: Bernhard Slaap, Jan Busschbach, Elly Stolk, Kristina Secnik Boye

Appendix I: Responsibility matrix for the UK EQ-VT study

	Study team	EQ-VT support team	QC team	Steering Group	EuroQol Executive Committee
Protocol and analysis plan					
Write documents	X				
Assist in writing documents		X			
Review final documents			X	X	
Perform QC on final documents			X		
Approve documents and funding					X
Sign off on final document				X	
Preparation and pilot data collection phase					
Deliver EQ-VT software		X			
Train interviewers	X	X			
Each interviewer conduct a series of pilot interviews	X				
Approve interviewers for real data collection	X	X			
Sign off on pilot data collection phase				X	
Data collection phase					
Perform interviews	X				
Prepare and discuss weekly QC reports		X			
Conduct two interim analyses	X	X			
Review interim analysis reports				X	
Perform QC on interim analysis reports			X		
Decide to continue as planned, retrain interviewers or amend study protocol				X	
If needed, approve extra funding					X
Perform QC on complete data set			X		
Review complete data set and QC report				X	

	Study team	EQ-VT support team	QC team	Steering Group	EuroQol Executive Committee
Sign off final data set for modelling				**X**	
Data modelling phase					
Perform modelling as specified in analysis plan and propose a final model	**X**				
Perform QC on modelling results, including proposed final model			**X**		
Review modelling results, including proposed final model and QC report				**X**	**X**
Sign off final model				**X**	
Reporting					
Write manuscript(s)	**X**				
Review and approve manuscript(s) for submission				**X**	
Approve study report and final payment					**X**