



EQ-5D

EQ-5D User License Policy

Procedure and fee structure

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The information in this document is subject to change without notice and shall not be deemed as a warranty by the EuroQol Research Foundation.

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Table of Contents

1.	Using EQ-5D.....	3
1.1.	General.....	3
1.2.	Requesting permission.....	3
1.3.	Non-commercial use (research).....	3
1.4.	Non-commercial use (non-research).....	4
1.5.	Non-commercial use (duration of study or project).....	4
1.6.	Non-commercial use of digital versions.....	5
1.7.	Commercial use.....	5
1.7.1.	Fee structure commercial use.....	5
1.7.2.	Multiple modes of administration.....	6
1.7.3.	Discounts for using several Modes of Administration (MOAs).....	6
1.8.	Third Party agreements.....	7
2.	Translation process.....	7
2.1.	EQ-5D translations.....	7
2.2.	Managing the translation process.....	7
2.3.	Requesting new language versions.....	8
2.4.	Translation costs.....	8
3.	Intellectual Property Rights.....	8
4.	Contact information.....	9

1. Using EQ-5D

1.1. General

The EuroQol Research Foundation is the copyright holder of the EQ-5D. If you would like to use the EQ-5D, written permission from the EuroQol Research Foundation should be obtained.

The EQ-5D is available in a 3-level (3L) and 5-level (5L) version for adults and a 3-level version for the youth (Y). The EQ-5D is primarily designed for self-completion, on paper or as a digital version. Several other modes of administration are available including interviewer-administered and proxy-administered versions (scripts for completion by observers).

The EuroQol Research Foundation is a registered charity in the Netherlands and serves as the single point of distribution of the family of EQ-5D instruments. The vast majority of requests to use the EQ-5D are fulfilled free of charge. In instances outlined below where license fees are charged, this source of income allows the EuroQol Research Foundation to fund activities in line with its Vision and Mission as described on its website. Main activities include, but are not limited to, funding research projects, organizing scientific meetings and providing support to EQ-5D users.

1.2. Requesting permission

A request to use the EQ-5D is initiated by filling out the registration form at the EuroQol website. Thereafter, the EuroQol Research Foundation's Legal Department will determine the applicable policy and respond with more information on how the EQ-5D can be obtained. Consultancies / CROs are required to disclose the name of the sponsor during or after the registration in order to check available active license agreements.

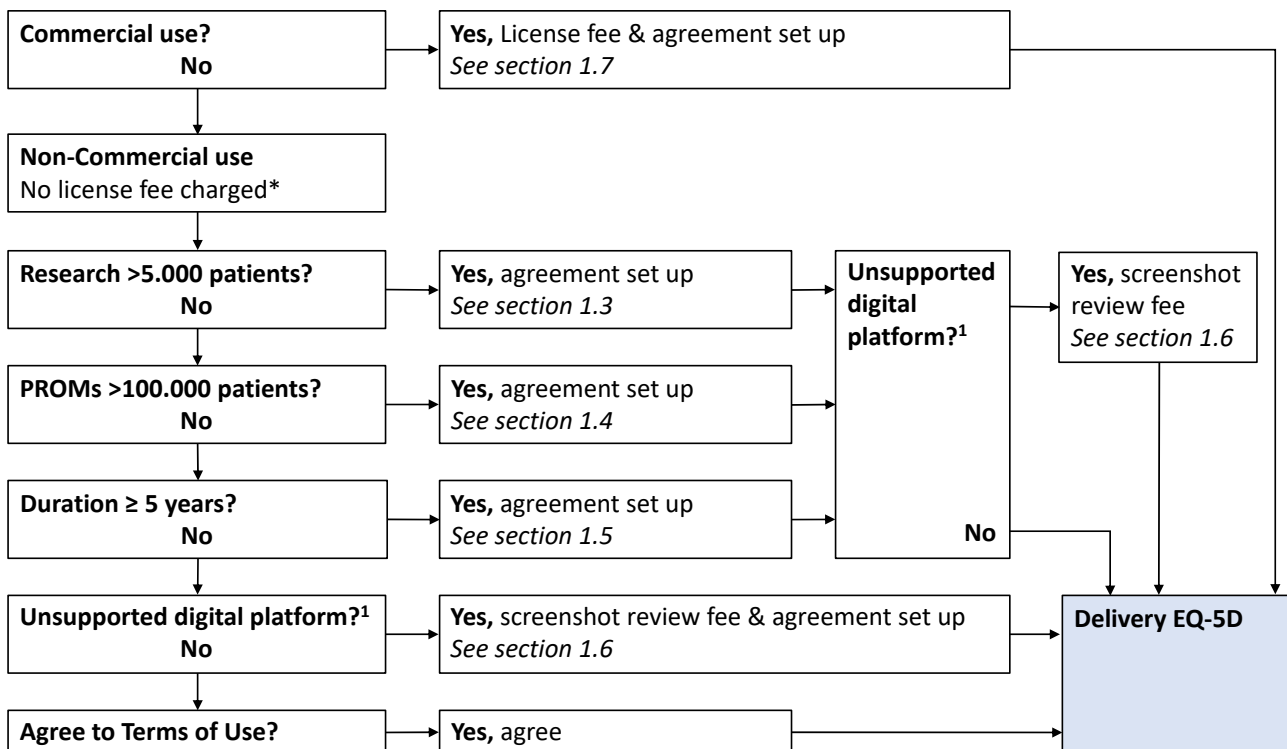
Depending on the request, a license agreement will be drawn up or acceptance of our Non-commercial Terms of Use will be required. For a flowchart of the User License Policy, see Diagram 1.

Delivery of requested EQ-5D versions will take place via a custom Internet Portal which customers can access during the agreed period, which typically is 3 years.

1.3. Non-commercial use (research)

In case of non-commercial requests to use the EQ-5D for research purposes, such as RCTs, cohort studies, case control studies and cross-sectional studies, no license fee is charged to use the EQ-5D. The rationale is that such use is in line with the EuroQol Research Foundation's Mission; this use will result in new publications on EQ-5D, which is of benefit to the EuroQol Group and its members, and to the scientific community as a whole.

For large studies and registries (N > 5000), additional terms may apply. These terms could involve a statement that the licensee will kindly review future requests from individual EuroQol members for research collaboration and data sharing. Considering that the EQ-5D is provided free of charge for this substantial data collection, such a request for research collaboration or data sharing should not result in fees being charged to the EQ member.

Diagram 1: Flowchart User License Policy

*: Except when EQ-5D data is collected with the intention to charge a fee for access;

¹: Platform for which no digital modules are available.

1.4. Non-commercial use (non-research)

In case of non-commercial requests to use the EQ-5D for non-research purposes, such as case series (clinical series) and case reports, for benchmarking, reporting to authorities, or for Routine Outcome Measurement (ROM), no license fee is charged to use the EQ-5D.

This includes use of EQ-5D by hospitals, clinics and health insurance companies, both publicly and privately funded. However, when the intention is to commercialize the collected EQ-5D data, the commercial policy will be applicable (as mentioned in 1.7 of this User License Policy).

For very substantial projects involving > 100,000 patients, a license agreement will be drawn up at no cost. At the discretion of the Board of the EuroQol Research Foundation, special arrangements may be put in place for these very substantial projects, such as research collaboration and/or collaborative research funding.

These non-research applications of the EQ-5D are in line with the Vision of the EuroQol Research Foundation, which is to improve decisions about health and health care throughout the world.

1.5. Non-commercial use (duration of study or project)

In case of a non-commercial request to use EQ-5D for a duration of > 5 years a license agreement will be drawn up at no cost. The maximum term for which permission can be arranged is 10 years. Users are

requested to re-register after this term to be entitled to continued use of the EQ-5D.

1.6. Non-commercial use of digital versions

The EuroQol Research Foundation is developing modular digital EQ-5D versions for use on popular survey platforms such as REDCap, LimeSurvey and Castor EDC. These modular digital versions for supported digital platforms can be used free of charge for non-commercial use. Upon acceptance of the Terms of Use the requested EQ-5D modules will be provided, as well as a guidance document. Please see chapter 2 if your requested EQ-5D module is not available.

The user is responsible for the correct representation of EQ-5D. Reference case EQ-5D representations can be found on the EuroQol website (<https://euroqol.org/eq-5d-instruments/sample-demo/>).

For the use of digital EQ-5D versions on currently unsupported digital platforms, for which no modular digital versions are available, a license agreement will be drawn up and a one-time screenshot review fee will be charged of € 600 to compensate for the resources needed to review and approve the screen shots. Please contact the EuroQol Office if you do not have a budget for the screenshot review fee.

1.7. Commercial use

In case a request is made by or on behalf of a pharmaceutical company, medical device manufacturer or any other for-profit stakeholder, the active license agreements will be checked and a license fee proposed, if applicable. If the proposal is acceptable, a new license agreement or amendment in case of existing agreements will be established between the company and the EuroQol Research Foundation. Such license agreement will specify which versions and languages of the EQ-5D (3L, 5L or Y) can be used. The agreement is limited to a single mode of administration.

Companies can obtain permission to use the EQ-5D in certain languages for a given mode of administration in all (clinical) studies starting during a period of three years. A "Fixed Price Agreement" can be purchased by companies wishing to access all available EQ-5D languages of the EQ-5D-3L, EQ-5D-5L or EQ-5D-Y in a given mode of administration. Once the license agreement has been fully executed, the EuroQol Research Foundation will deliver the licensed languages in MS Word, PDF or MS Excel format via a custom Internet Portal that will be accessible for three years. Finally, the invoice will be delivered according to the instructions in the license agreement.

1.7.1. Fee structure commercial use

The fees of a license agreement are organized per EQ-5D version, e.g. EQ-5D-3L, EQ-5D-5L or EQ-5D-Y on a "per language and per mode of administration" basis. The available languages are validated for use in a specific country and are quoted as such.

The available modes of administration are:

- Self-complete version on paper
- Self-complete version on PDAs/Smartphones
- Self-complete version on Tablets
- Self-complete version on Laptops/Desktops
- Interviewer-administered versions
- Proxy-administered versions

Companies that wish to have access to **all** available languages (as well as those becoming available within the three years license agreement of a particular mode of administration) may request a "Fixed Price Agreement".

The fee for a 3-year license agreement to use the EQ-5D-3L, EQ-5D-5L or EQ-5D-Y is as follows:

1. Per language / mode of administration	€ 3,500.00
2. Exception: Same language / mode of administration, but different country	€ 1,750.00
3. Fixed Price Agreement / mode of administration	€ 75,000.00

Note for companies interested in collecting EQ-5D data with the intention to commercialize (e.g., resell) this data, the fee structure noted above will not be followed. Instead, the fee will be determined by the EuroQol Office based upon the size and scope of the request.

1.7.2. Multiple modes of administration

In instances where a company requests various Fixed Price Agreements for digital modes of administration (Tablet, PDA/Smartphone or Laptop/Desktop) or interviewer-administered versions, a discount rate will be applied. Please note that these discounts for extra modes of administration (MOAs) are applied only across modes of administration of the same EQ-5D version, e.g. EQ-5D-3L, EQ-5D-5L or EQ-5D-Y.

Please find the discount table below:

1.7.3. Discounts for using several Modes of Administration (MOAs)

Table 1. Discount-table Paper vs. Digital (Percentages)

	Paper	Extra MOA #1	Extra MOA #2	Extra MOA #3
Fixed Price Agreement (FPA)	0%	0%	25%	50%

Table 2. Discount-table Paper vs. Digital (Euros)

	Paper	Extra MOA #1	Extra MOA #2	Extra MOA #3
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Fixed Price Agreement (FPA)	€ 75.000,00	€ 75.000,00	€56.250,00	€ 37.500,00
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1.8. Third Party agreements

Third parties are entitled to administer the EQ-5D on behalf of a commercial entity after signing a free of charge third party agreement. Such a third party agreement enables the consultancy / CRO / vendor to facilitate the use of EQ-5D languages in a specific study, trial or project. The requested EQ-5D languages will be provided to the third party via a custom Internet Portal only once the EuroQol Research Foundation receives the signed third party agreement. Please note that clinical study sites are exempt from third party agreements.

The license agreement will always be between the company concerned and the EuroQol Research Foundation. Negotiations regarding the license agreement can proceed via the consultancy / CRO, if preferred.

2. Translation process

2.1. EQ-5D translations

The EuroQol Research Foundation will explore the feasibility of translating EQ-5D into currently unavailable languages upon request. Assuming that our translation agencies indicate resources to be available to arrange such, EuroQol will lead the translation project. All translations/adaptations of EQ-5D are produced according to our standardized translation protocol, which complies with internationally recognized guidelines. These guidelines aim to ensure equivalence to the 'source' version and consists of, inter alia, a forward/backward translation process and cognitive debriefing.

The value of the EQ-5D to users is that the multitude of versions and languages allows for multi-country and within-country trials. Such will only be possible if there is congruence between the versions in terms of the content and layout, and if the results obtained using the same version in different languages will be interchangeable.

2.2. Managing the translation process

The Version Management Committee (VMC) of the EuroQol Research Foundation is responsible for the quality of the translation process of all EQ-5D language versions.

Whereas it is not the role of the VMC to undertake any translations themselves, it is their role to ensure that every translation of every version be as consistent as possible with all the other versions, while using phrasing appropriate to the country, the language and the age group.

The VMC project management at the EuroQol Office supports the VMC and manages the operational side of the translation work and the communication with users. Their remit includes: i) project management, ii) archiving and tracking of language versions of the questionnaire in all formats; iii) overseeing production of translation certificates; iv) quality control of screenshots for electronic versions.

2.3. Requesting new language versions

Please complete the Registration Form on the EuroQol Research Foundation's website if you would like to obtain an EQ-5D version that is not available according to the overviews on this website.

Once the Translation Request is qualified the VMC project management team will consult our translation agencies in order to determine the following aspects:

- whether the requested translation(s) can be delivered,
- if the requested translation(s) can be delivered within your deadline, and
- what the costs of the translation(s) will be.

If you agree with the translation costs and the estimated delivery date(s), you will have to sign an Approval Letter to initiate the translation process. Once the Approval Letter is signed and the EuroQol Office confirms receipt, the translation process will start. Hereafter, cancellation costs may apply if you decide to cancel the translation project.

2.4. Translation costs

In principle, translation costs for new language versions are covered by the user requesting the new version. In exceptional cases, at the discretion of the EuroQol Research Foundation, non-commercial users will be offered a waiver for (part of) the translation costs. Please contact the EuroQol Office for more information.

3. Intellectual Property Rights

All intellectual property rights in the EQ-5D, its (digital) representations, and its translations exclusively vest in the EuroQol Research Foundation. Without the prior written consent of the EuroQol Research Foundation, it is not permitted to i.e. use, reproduce, alter, amend, convert, translate, publish or make available in any way (digital, hard-copy etc.) the EQ-5D, or parts thereof, and related proprietary materials. When permission is obtained to reproduce or publish the EQ-5D, please use the following copyright and trade mark statement:

© EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation.

4. Contact information

For further questions and/or information regarding the EQ-5D Users' Policy, please contact the EuroQol Office at the following address and contact details:

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