eCOA LICENSING: LESSONS LEARNED FROM THE COPYRIGHT OF COA TRANSLATIONS AND SPECIFICITIES OF eCOAs

Caroline Anfray[1], Katrin Conway[2], Catherine Acquadro[2]
[1]Mapi Linguistic Validation, Lyon, France; [2]Mapi Research Trust, Lyon, France

Background and Objectives

- It is worth mentioning that, in 2007, of 3,000 occasions on which developers, publishers, or users of PRO instruments submitted requests for information or asked for help from the Mapi Research Trust's PRO Information Support Team,[1] 38% were questions about copyright or conditions of use. The most frequently asked questions were: "Who should be contacted to get permission to use a questionnaire, an existing translation or to develop a new translation of a PRO questionnaire?" or "Who is the copyright holder?" Thirty-four percent were about practical information about the instruments with questions such as: "Is this the latest version of the instrument?", "Does the translation reflect the original questionnaire?" or "Is the translation validated?"
- In 2014, the PRO Information Support Team continues to receive the same questions, except that a new parameter has appeared, i.e., the mode of data collection through an electronic device, e.g., "Is *an electronic version* of this instrument available?" or "Have the instrument translations been validated *on an electronic device* yet?" echoing the recommendations in the field.[2]
- In 2007, the questions about electronic Clinical Outcome Assessments (e-COAs) represented just 7% of the entire requests made to our library. Today, they represent over 27% of the requests coming from the pharmaceutical industry and 18% of the requests from academia.
- The Mapi team[3] – as well as Revicki and Schwartz[4] – has detailed important reasons for developers to exercise their rights, in particular *"the maintenance of the scientific integrity of the copyrighted instrument which will ensure researchers and readers of scientific journals that the study used the correct version and that there is evidence supporting the psychometric qualities of the instrument."* In the light of the FDA guidance[5], the latter is of special relevance. Copyright has proven to be one of the most efficient means for developers of COAs to maintain the integrity of their instruments by controlling their access and use.
- The trend to increasingly rely on electronic data capture has made the notoriously difficult question about copyright even more intricate through the addition of specialized device and software companies to the development team.
- The objective of this abstract is to make recommendations about eCOA licensing using lessons learned from other situations, such as the COA translation licensing.

Methods

- Publications about licensing of COA translations were searched and a review of the eCOAs specificities was performed using information available from e-vendors.

Results

- The use of a COA is linked to the identification of its *author* who shall then be the *copyright owner* and who is the only person entitled to grant permission. However, in some cases, the identification of the COA copyright owner can be a hurdle since an original ownership can be shared, transferred, or assigned – either intentionally or not (see Table 1).

Table 1. Issues in the identification of copyright owner of an original COA

Questionnaire's life	Who may claim copyright?
Development	Individual experts (academics), Sponsor (work made for hire) University? Joint authorship?
Communication, publication	Publishers? Journals?
Derivative works: • Adaptation/ modification of original • Translations • E-versions	Original copyright holder? Translators? Translation companies? Sponsors? E-vendors?

- Our review showed that very few publications[6-7] exist about the licensing of COA translations.
- The ISOQOL TCA SIG has developed a reflection paper,[8] (not yet published), which considers that translations are derivative work of original questionnaires. In this paper, they review the basics of copyright and important information about translators and translations of PROs.

Translators are protected by copyright national laws. For instance, Article L. 112-3 of the French CPI stipulates that the authors of translations benefit from the *same rights* given to authors by virtue of the present code, without prejudice to the rights of the author of the original. On an international level, UNESCO has adopted a recommendation, which specifies that: *"Member States should accord to translators, in respect of their translations, the protection accorded to authors under the provisions of the international copyright conventions to which they are party and/or under their national laws, but without prejudice to the rights of the authors of the original works translated."*[7]

Therefore, in the absence of any statement from the owner of the original questionnaire that he/she wants to own the copyright on translations of his/her questionnaire or of a written contract between the parties involved, the translator is the copyright owner of the translation.

One of the risks to developers who do not control the translations of their original questionnaires is the multiplication of "same language" translations (i.e., different Spanish versions of the same original). In this case, it is almost impossible to identify the "right" translation. In the context of international clinical trials, this situation can be very problematic for users and generate unnecessary delays and extra costs if a new translation should be developed. From a copyright perspective, it could be possible to develop several translations for a same language and country, but in opposition, our domain requires that a translation for a given language shall be unique, in order to further its validation, and shall be shared across users for harmonization purposes and comparison of data.

That's why a centralized ownership has proven to be extremely efficient to protect the instrument and how it is used globally, because its use and its users can be properly tracked. Also by keeping control in this manner, updated and reliable information on the instruments can be provided to new and former users.

Recommendation to developers of COAs
The owner of the original COA is key in determining the future of the instrument and in protecting its integrity globally by controlling access and use. It is recommended that ownership of translations should be centralized to the copyright owner of the original COA and this should be stated in writing.

Specificities of eCOAs

eCOAs are often adapted from paper-based measures.

eCOA data collection implies:

(a) the use of data-collection software, (b) a data-collection device, and (c) changes to the content and format of the paper version following the migration from paper to an electronic platform/device.[2]

In terms of copyright, eCOAs derived from paper versions are an adaptation of the original and can be considered as derivative works, like translations. Ideally, the lessons learned from the copyright of translations should apply: (a) the owner of the original instrument is key in determining the future of the e-versions of his/her instrument, and (b) copyright is crucial for preserving the integrity of the measure and its e-versions.

However, some pitfalls that are specific to the e-domain exist:

- Ownership is unclear – a mixing of rights (questionnaire/device/software)
- eCOAs are customized, and cannot be shared across users
- Equivalence, not only between paper and e-version, but also between e-versions, should be addressed
- There is a multiplication of e-versions for the same content
- Certifications of paper versions do not apply to e-versions
- Where to find relevant information? Who should be contacted?

To summarize, lessons learned from the copyright of translations may indeed apply partly to the copyright of eCOAs.

We believe that centralized copyright ownership on the *content* and a centralized licensing process for eCOAs by the owner of the original paper version may be helpful to:

- Control use and users (sub-licensees)
- Protect the integrity of the instrument across e-versions by providing clear rules of electronic implementation
- Harmonize the electronic validation procedures across e-vendors
- Centralize reliable information on the eCOA versions

References

1. Anfray C, Emery MP. Access and use of Patient-Reported Outcomes (PRO) instruments in international studies: authorship and copyright issues. Presented at the 14th Annual Conference of the International Society for Quality of Life Research (ISOQOL), Toronto, Canada, October 10, 2007.
2. Coons SJ, Gwaltney CJ, Hays RD, et al. Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO Good Research Practices Task Force Report. Value Health 2009;12:419-29. Available from: http://www.ispor.org/workpaper/patient_reported_outcomes/Coons.pdf
3. Anfray C. Patient-reported outcomes instruments: bridging the gap between international copyright laws and common practice for developers and users - a case example. Qual Life Res 2009;18(10):1281-1283.
4. Revicki DA, Schwartz CE. Intellectual property rights and good research practice. Qual Life Res 2009;18(10):1279-1280.
5. US Department of Health. Food and Drug Administration. Patient-reported outcome measures: use in medical product development to support labeling claims. Federal Register 2009;74(35):65132-133. Available at [http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf]
6. Anfray C, Emery MP, Conway K. Acquadro C . Questions of copyright. Health Qual Life Outcomes 2012;10,16.
7. Anfray C, Eremenco S, Patrick DL, Conway K, Acquadro C. Copyright of translations of PRO measures: rules and applications. [abstract], Quality of Life Research 2010;19(suppl 1), A-37.
8. Anfray C, Arnold B, Martin M, Eremenco S, Patrick DL, Conway K, Acquadro C on behalf of the ISOQOL Translation and Cultural Special Interest Group (TCA SIG). Reflection paper on copyright, patient-reported outcome measures and their translations. Submitted.

Conclusions

Centralized copyright ownership by the owner of the original COA and centralized licensing process for eCOAs should be discussed with all stakeholders to help controlling use and users and to protect the integrity of the instrument across e-versions by providing clear rules of e-implementation.

For more information, please contact:
Caroline Anfray
canfray@mapigroup.com

www.mapigroup.com

ISPOR 17th Annual European Congress
8-12 NOVEMBER 2014, AMSTERDAM RAI, AMSTERDAM, THE NETHERLANDS