

Roche automated esub translation

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Abstract

Esub translation is one of the final steps in the end-to-end process of clinical trial development. At Roche, the esub translation and review works are time-consuming and repetitive. Our team has been focusing on improving several aspects of the process to achieve high efficiency. In this talk, we will share our experience in

1. reducing interactive manual work.
2. avoiding repetitive translation work by mapping to the translated GDSR copies
3. improving translation review process efficiency by triaging and comparing translation results from multiple translation engines.
4. Quality comparison of AI translation results and other translation engine models.

Motivation

As the final step of regulatory submission, China's health authority requires data translation as part of the eSub package. Machine translation is relatively fast these days, yet the quality and accuracy still require subject matter experts to review, which is time-consuming as tens of thousands of records go through.

Our approach

Our current eSub translation workflow operates independently from study to study, which creates many repetitive tasks at the end of the filing process. The pipeline requires multiple tools from different sources (shiny apps, local scripts, and external translation engines), which requires several manual steps. The biggest challenge is that the workflow relies on subject matter experts to review everything, which is time-consuming given the large amount of content. To improve the workflow, we designed specific improvement strategies. More specifically, we aim to

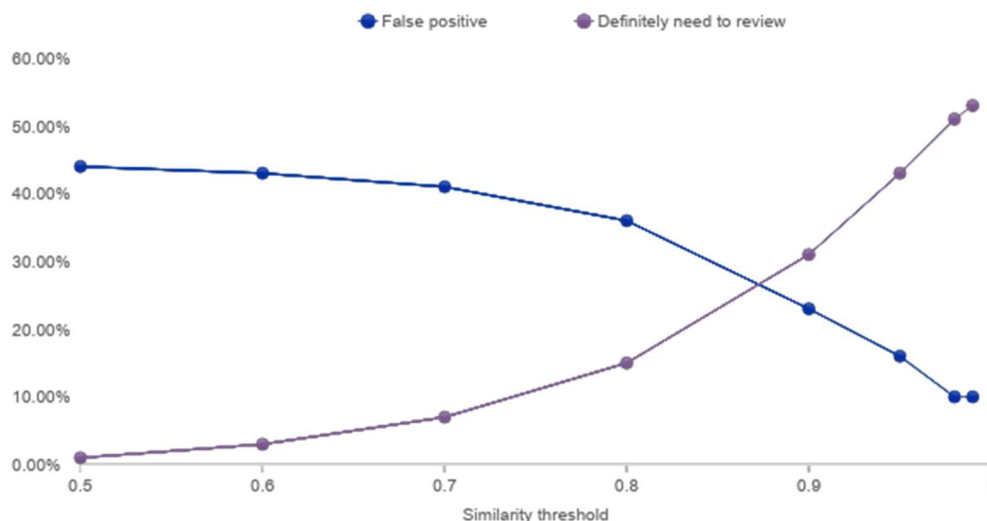
1. Utilize multiple translation engines to triage translation results.
2. Reduce manual file manipulation and transfers by using a single system.
3. Replace manual file submission to translation engines with automation.
4. Reuse past experience and the translated files via a version-controlled translation database.

Triage of machine-automated translation outcome (TOMATO)

We use three translation engines, namely iTranslate, DNA translate, and Supercat to translate, and a separate NLP model to make three pairwise comparisons of the translation, and derive similarity scores. We set a similarity score threshold at 95%, and the similarity scores will lead to four scenarios:

1. If all three pairs are similar to each other, we consider all three translations to be equally good quality and will skip manual review.
2. If one pair has a high similarity score that passes the threshold, but the other two pairs have lower scores. We consider the two translation engines can take a majority vote, and we can skip the review (or a modest review should be sufficient.)
3. If all three pairs are dissimilar to each other, translations for this entry will be reviewed.
4. If translation engine A is similar to B, B is similar to C, but A is not similar to C. Such translations will be reviewed manually though these cases are relatively rare.

A higher similarity threshold will lead to fewer entries passing the machine's automatic review and more work for manual reviews. On the other hand, setting a lower threshold will allow more entries to pass but with a higher false positive rate, which means we are more likely to miss some translation results that require reviews and corrections. At the end of the day, we aim to balance the reviewing time while still maintaining qualified translation.



Version-controlled GDSR translation

In our translation process, we found that at least 65% of the defined file entries (SDTM and ADaM) can be mapped to the GDSR, which means, 65% of translation work can be simplified by taking the GDSR translation. Therefore, part of the new translation automation involves translating and updating GDSR, which continues to evolve and extend in scope for use across Roche's clinical operations.

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