BALANCING INNOVATION AND PROPRIETY:
The Question of Copyright Holders' Opinions on GenAI Usage While Localizing Their Intellectual Property

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OBJECTIVE

The question of integration of Generative Artificial Intelligence (GenAI) into clinical trial operations, particularly concerning Clinical Outcome Assessments (COA), is hampered by a lack of clear guidance regarding GenAI's application to COA intellectual property (IP). This uncertainty has slowed the adoption of GenAI in critical areas such as COA linguistic validation and migration, which are vital for incorporating the patient voice. **This study aimed to collect and disseminate COA copyright holders' perspectives on GenAI usages in these processes to inform future deployment strategies.**

METHODS

To reach this objective, an electronic 15-question survey covering the three topics below was sent to 100 COA copyright holders. Fourteen copyright holders replied to this anonymous survey within the three-week time frame provided.

- 1) Allowance and Confidence of AI-Usage in COA Translation (LV) and eCOA Migration (Migration)
- 2) Certifications and Trust
- 3) Current AI Approaches, Policies, and Licensing

RESULTS & INTERPRETATIONS

1) Allowance and Confidence of AI-Usage in LV, Migration

a. Results: 64% (9/14) of COA copyright holders who responded were Not at All Confident that AI could be used to translate their COA Measures within the Linguistic Validation Process. However, only 29% (4/14) were Not at All Likely to allow AI usage when translating their COA measures within the Linguistic Validation Process. The responses between Confidence and Allowance of AI usage within the eCOA Migration Process were much more aligned, with 29% (4/14) and 21% (3/14) being Not at All Confident and Not at All Likely, respectively.
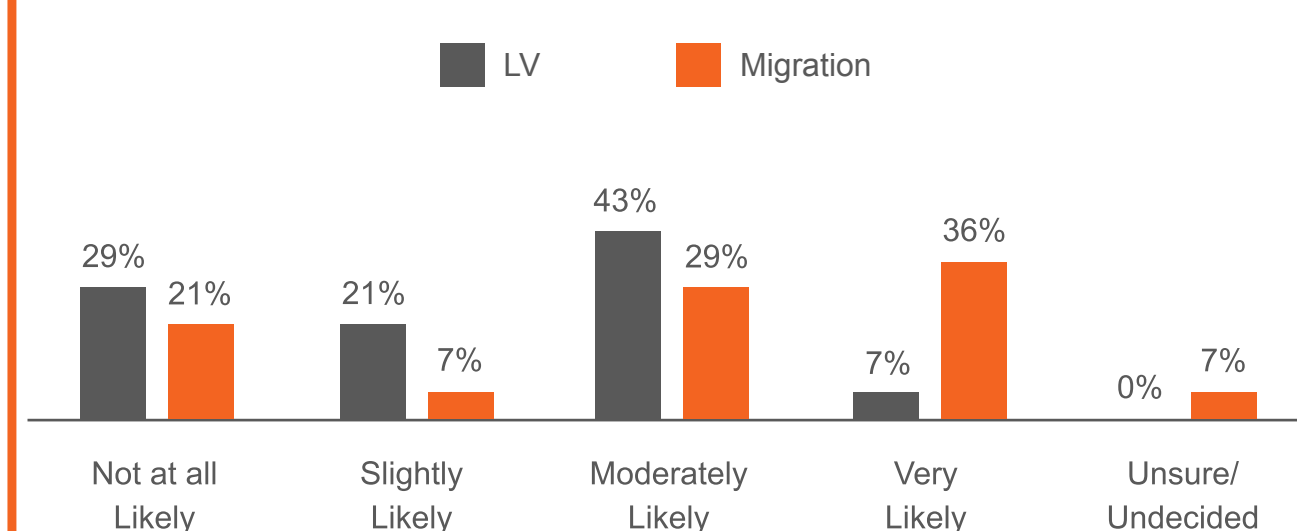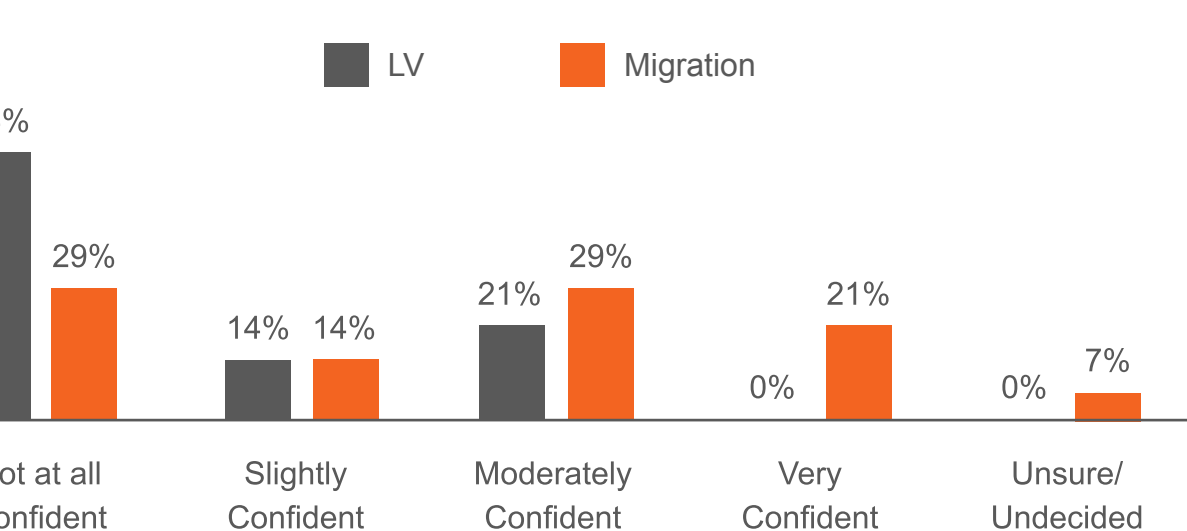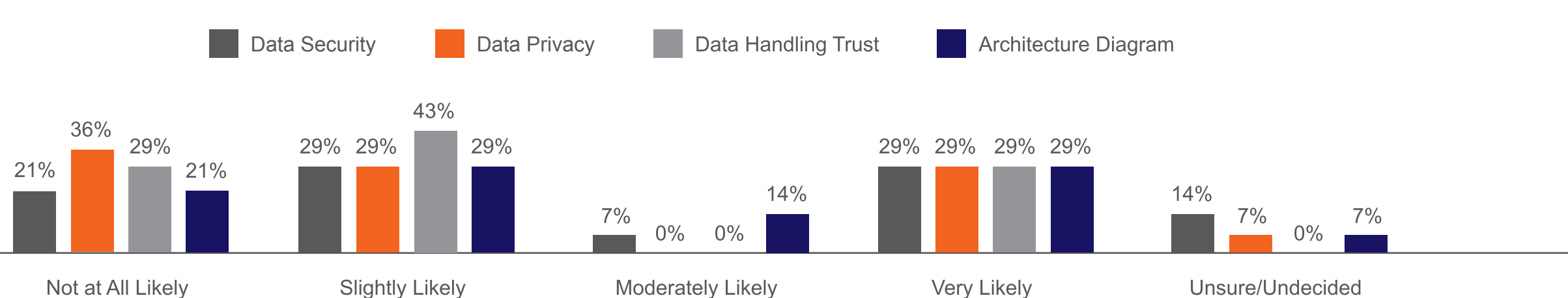

b. Interpretation: While copyright holder Confidence in AI's capabilities differed between usage within LV and Migration, the likelihood of allowing AI usage across these 2 workflows was consistently positive in likelihood to allow usage, though to varying degrees (Moderately v. Very), with LV being 50% (7/14) and Migration being 65% (9/14). According to Free Text Responses, Confidence is low overall. However, most respondents were willing to allow AI usage after a nuanced dialogue.

2) Certifications and Trust

a. Results: We checked with copyright holders on the impact (i.e., likelihood to approve AI-usage) of several certifications and/or documentation: 1) Data Security Certification (e.g., ISO27001:2022), 2) Data Privacy Certification (e.g., ISO27001:2019), 3) Data Handling Trust Certification (e.g., SOC2 Type 2), and 4) AI Architecture Diagram. The different certifications/documentation had mixed results, with the most skepticism on the impact of Data Privacy and Data Handling Trust. However, across all 4 types, 29% (4/14) of respondents were Very Likely to approve AI-Usage with this documentation in place.

b. Interpretation: While there is skepticism around different documentation types (certification/diagrams), data security, privacy, and how the AI engine functions, these documentation types do increase the likelihood of at least 29% of copyright holders becoming more favorable towards AI usage when translating their IP.

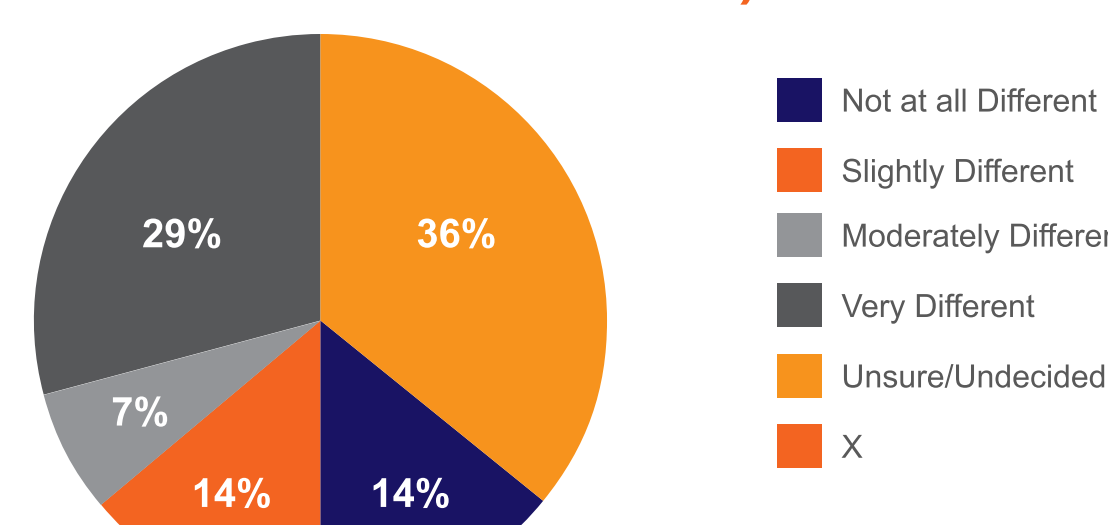### 3) Current AI Approaches

a. Results: Four (4) questions were asked on this topic.

1) When asked how different their approach to AI usage for LV and Migration would be compared to their approach to CAT-tool solution usage would be, a majority (36% (5/14)) were Unsure/ Undecided. In comparison, 28.5% (4/14) said they would be Very Different. Only 28.5% (4/14) said they would not approach this technology Differently or only Slightly Differently compared to CAT-tool technology.
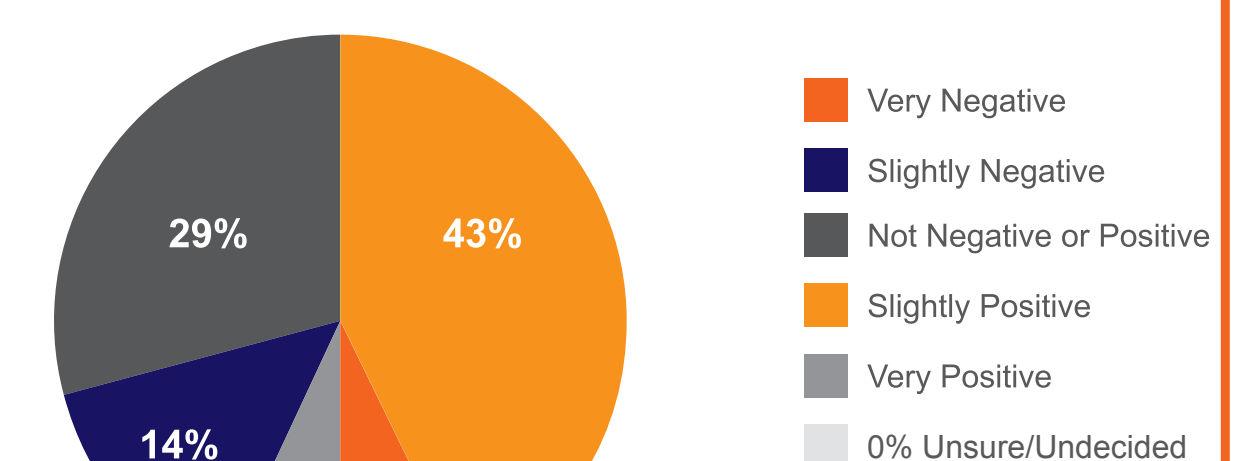
2) 43% (6/14) felt that AI usage within Clinical Trial and Translation was Slightly Positive, followed by 29% (4/14) being Not Negative or Positive. Very Negative and Very Positive had similar results of 7% (1/14), while the remaining 14% (2) respondents felt Slightly Negative.

3,4) When asked if they were proactively providing AI usage policies in publicly available forums, 72% (10/14) said "No." In addition, 86% (12/14) have not adapted their license agreements to clarify their policies on AI usage.
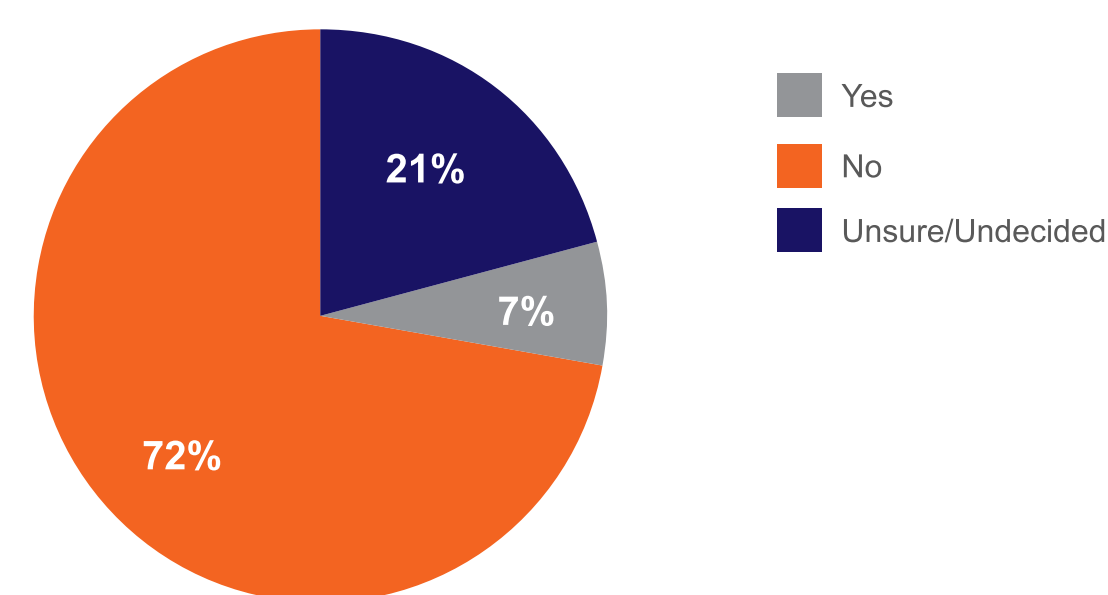

b. Interpretation: There appears to be some uncertainty in how this technology differs from older technology used in translation and how to adjust approaches with that level of difference in mind. There is also a wide spectrum of opinions surrounding AI usage within the industry. However, the most salient result on this topic, and potentially from the full survey, was the lack of proactivity in informing potential licensees of AI policies surrounding the use of their IP, even in documentation within the license agreements themselves. However, this will soon change according to Free Text Responses, so this study group recommends that licensees assume that a lack of information means a lack of opinion or policy when engaging with copyright holders.

CONCLUSION

Copyright holders of COA measures are navigating an industry that still lacks clear guidance on AI usage when localizing their IP, just like other stakeholders. However, while there is room to improve these stakeholders' confidence in appropriate AI usage when localizing their IP, they **appear to be open to discussions, policy creation, license agreement amendments, and reviewing documentation to verify the security of their IP when interacting with an AI engine**. As a final note, the number of respondents limited this study, and further analysis will be needed to verify these results.