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Wednesday, October 4, 2023

Customers, collaborators, and partners,

Recently Translational Software (TSI) was denied a FDA 510(k) application for medical device status for their laboratory software solution. As a result, they will be discontinuing their PGx reporting services. This has left their existing customers, and the industry as a whole, with some uncertainty as to how laboratories can continue to serve the researchers, medical professionals, and other interested parties with PGx-related insights. It has also brought to question the differences between the services provided by TSI and Coriell Life Sciences (CLS). Here are some details.

1. Unlike the TSI PGxPortal solution, CLS does not provide services in the production of clinical laboratory reporting. Laboratories who offer genetic variation testing of known pharmacogenomic genes must produce and report their results, as measured by their validated processes and equipment. Those results must adhere to all applicable regulations and standards related to molecular diagnostics according to the accreditation organization(s) to which they subscribe.

2. CLS is a company that provides general purpose research services. As such, it has worked for more than 10 years to curate published literature, consortium evidence, standards organization findings, and other reference information to provide users with relevant medical reference information related to pharmacogenomic variations. CLS analyses are intended for educational and research purposes only.

3. CLS performs a meta-analysis of the available research literature using a process of evidence assessment that has been published and peer-reviewed[1]. The ultimate findings of that meta-analysis are presented for consideration as the professional opinion of the CLS research team.

4. Laboratories and other users may opt to engage with CLS to create a research analysis of specific gene variations. The variations are aligned to the meta-analysis results for each gene:drug pairing. The resulting research analysis is distinct from the CLIA reporting of genetic variations from the laboratory. It exists as a 3rd party literature review from professional researchers. The analysis is not intended to provide clinical reporting, but rather to quickly surface relevant medical reference information that may be educational for its users.

5. All CLS guidance is transparent and cited with the published literature references available for independent review.

6. The CLS literature research analysis also makes clear that the state of knowledge in pharmacogenomics is not fixed. New literature that refines previously published guidance, or provides wholly new guidance, is published continually. Researchers and other users who utilize PGx reference information, including any meta-analysis information generated by CLS, should do so with the full knowledge of these limitations.

[1] Gharani, N., Keller, M.A., Stack, C.B. *et al.* The Coriell personalized medicine collaborative pharmacogenomics appraisal, evidence scoring and interpretation system. *Genome Med* **5**, 93 (2013). https://doi.org/10.1186/gm499

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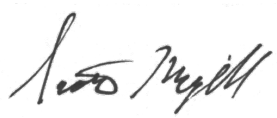
As a consultative research organization, CLS is not pursuing a 510(k) filing for its research services. CLS does allow for automated literature reference analysis for laboratories, research organizations, and business partners who support our ongoing research efforts. Partners can invoke the CLS cloud-hosted knowledge repository using our published API to receive a research alignment analysis for specific genetic variations.

Please do not hesitate to reach out to myself or Dr. Jeffrey Shaman, our CSO, to discuss how we can partner together to jointly empower users with research insights.



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