



January 2015

Position Statement on Licensed Databases and Plans for the Global Sharing of Variant Data

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Genetic testing from single gene to genome scale sequence analysis is more frequently being offered in the clinical setting. However, the *same* variants are sometimes interpreted *differently* across laboratories. In addition, the majority of variants have insufficient evidence for a definitive classification and the proportion of those unclassified variants varies over populations. As a result, there is a significant risk that patients could be harmed by medical decisions made based upon unsubstantiated variant classifications or insufficient data on identified variants. Given the rarity of most variants of clinical relevance, it is imperative that all data on variants is fully shared to improve our understanding of genomic variation and the resulting patient care activities that are reliant on this information. The genomics community has already recognized and embraced global data sharing as a critical component of knowledge generation to support both knowledge discovery and translation of findings that maximize the utility of genomic testing for clinical use in different populations.

ClinGen investigators do not endorse the licensing and monetization of variant databases, which should be considered pre-competitive, and instead support the broadest sharing of data to ensure patient safety. The following are specific concerns about licensing and commercializing variant databases:

- Separating data into commercialized and non-commercialized databases will limit the full aggregation of data and reduce the ability to learn most effectively from the data and efficient comparative analyses. Allowing any variant data to be "sold" will broadly inhibit data sharing as many data sources may not share data in hopes of profiting from their data.
- Ability to access commercialized databases will vary according to the financial capabilities of groups, creating disparity in the medical community and other consumers of the data.
- Restricting data sharing is contrary to best practices of medical care and is unethical according to multiple resolutions adopted by the American Medical Association.

Thank you for consideration of our comments. Please do not hesitate to contact us with questions.

Sincerely,
ClinGen Principal Investigators