

## ClinGen Variant Curation Training, Level 2 (VCEP-specific)

Version 1, Approved: June 19, 2019

Level 2 variant curation training aims to educate the biocurator on the specific ACMG/AMP guideline specifications and variant assessment procedures outlined by their assigned variant curation expert panel (VCEP). Level 2 training begins after a biocurator has attested to completing all aspects of the general, VCEP-agnostic [Level 1 training](#). Documentation of Level 2 training activities will be kept in a personalized folder within ClinGen's "Variant Curation" Google drive. Variant biocurators will receive a link to their personal folder upon completion of Level 1 training.

Variant biocurators may join VCEPs through different avenues (recruited by a VCEP chair, volunteered through the ClinGen Community Curation working group, etc.) and with differing levels of experience (novices, variant scientists, clinical laboratory directors, etc.). Level 2 variant curation training should take this into account.

The first step in Level 2 variant curation training is to review the individual VCEP's ACMG/AMP sequence variant interpretation guideline specifications. This is mandatory for all group members, regardless of the level of expertise. For newly formed VCEPs, the guideline specifications may be in draft form. A copy of the VCEP's guideline specifications will be provided by the VCEP coordinator.

In order to complete Level 2 variant curation training, individuals must demonstrate proficiency in the following three areas:

- Evidence identification
- Documentation of evidence into the Variant Curation Interface (VCI) for review
- Assessment of the significance of evidence in accordance with the VCEP criteria

### *Biocurators with limited variant curation experience*

For a biocurator who has never curated with a VCEP before and has little prior variant curation experience, the biocurator must perform each of the three activities listed above on at least five variants before being considered sufficiently trained to begin curation on their own as part of the VCEP. *Please note: All curations are reviewed and approved by a VCEP before they are made publicly available; at no point, even after training is completed, should a biocurator "approve" a variant curation without prior discussion with the VCEP.* There may be slight variation in each VCEP's variant review and approval process. See [VCEP Protocol](#) documentation Section 3.1, page 15.

- Each individual VCEP will determine which variants a new trainee curator will evaluate. VCEPs may choose to use a predetermined set of training variants (previously curated by the VCEP) or to have trainee curators perform dual curation on variants not previously assessed, in parallel with a trainer.
- In order to allow flexibility, the activities may be performed in different combinations across different variants (e.g., identifying the evidence for 5 variants, assessing the evidence for 5 different variants, etc.) or all three activities can be completed for each of

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5 variants. However, at least two of the variants should be completed in full by the trainee biocurator (i.e., evidence identification, evidence assessment, and data entry).

- For example: A curator could perform evidence identification only for 3 variants, VCI entry only for 3 variants, evidence assessment only for 3 variants, and all three steps for 2 variants. Another curator could do all 3 steps for 5 variants. Both scenarios satisfy the training requirements.
- The variants used for training should be of different variant classifications and different variant types that meet a variety of ACMG/AMP evidence criteria.
- Completion of these variants will be documented in a tracking sheet located in the individual biocurator's Variant Curation Google Drive folder.

### *Biocurators with previous variant curation experience*

Some biocurators may join a VCEP with higher levels of experience in variant curation. These individuals are presumed to have good working knowledge of the general ACMG/AMP sequence variant interpretation guidelines, as well as the process of identifying and assessing variant evidence. In this case, the biocurator may go through an abbreviated Level 2 training process if they meet any of the following requirements.

- ABMGG certification (or equivalent) in Clinical Molecular Genetics and Genomics or Laboratory Genetics and Genomics
  - Documentation: Biocurator will provide copy of active certification, which will be kept in their Google Drive folder.

OR

- Employed by a clinical testing laboratory as a variant scientist, genetic counselor or trainee for at least 1 year. Primary job responsibilities include assessing variant evidence and providing preliminary or final variant classifications.
  - Documentation: Standardized template letter of attestation from lab director to sign, to be provided by biocurator. A copy of the signed letter will be kept in the biocurator's Google Drive folder.

OR

- Experienced ClinGen biocurator or staff scientist, working with ClinGen VCEPs and curating at least 30 variants (variants should be of different variant classifications and different variant types that meet a variety of ACMG/AMP evidence criteria) that have been reviewed and approved by any VCEP.
  - Documentation: Variant curation tracking sheet, located in their Variant Curation Google Drive folder. An example sheet may be viewed [here](#).

Upon joining a new VCEP, an experienced biocurator (i.e. meeting one of the requirements listed above) must curate at least 2 variants for their new VCEP (variants should be of different variant classifications and different variant types that meet a variety of ACMG/AMP evidence criteria) for review and approval by the VCEP in order to: A) demonstrate proficiency with the VCEP-specific ACMG/AMP sequence variant interpretation guidelines modifications and B) demonstrate proficiency using the ClinGen Variant Curation Interface (VCI). The VCEP will

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determine which variants new biocurators will curate. Upon review of the curations, the VCEP will determine whether the new biocurator is proficient or requires additional training through the continuation to the traditional 5 variant curations.

Experienced biocurators who meet the criteria above are eligible, but not obligated, to train new biocurators. Each VCEP will document which biocurators will train new biocurators and include these names in the annual EP update form.

For any newly forming VCEP we recommend that all pilot variants be evaluated by teams of 2 biocurators (also referred to as “dual curation”), regardless of the level of biocurator skill; this will help ensure that the curators are concordant with each other, and the specifications are performing as expected.

### Documentation

- Biocurators deemed proficient prior to June 19, 2019 may be grandfathered in without formally completing Level 1 and Level 2 training. Please have a VCEP chair complete this [form](#) and add that documentation to the biocurator personal folder in the [Variant Curation Google drive](#). Please contact Kelly Toner ([ktoner1@geisinger.edu](mailto:ktoner1@geisinger.edu)) if a new biocurator folder needs to be created.
- For any biocurator who will serve as a trainer for your VCEP, please have a VCEP chair complete this [certification](#) and add that documentation to the biocurator’s personal folder in the Google drive.
- For each biocurator going through Step 2 training, please track their progress using this template [Variant Curation Training Logbook](#). Once biocurators have completed Step 2 training, please have a VCEP chair complete this [form](#) and add that document to the biocurator’s personal folder.