Hotspot Clinical Pipeline

**User Requirements Specification (URS)**

**URS-HPS-0001**

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# Purpose

This User Requirements Specification (URS) captures, at a high level, the user requirements for the clinical pipeline functions, rules, and interfaces required to enable the system to perform its intended operations from the End Users’ perspective.

## Requirements Numbering

Requirements are grouped into related sections. Within each section requirements are numbered as they are assigned in JIRA software upon creation.

## Scope

This document enumerates the clinical sample data flow process the clinical pipeline from sequencing to report generation

## General Software Requirements

The general software requirements can be found in the Software Requirements Specification (SRS) section and in Appendix 2 of the Validation Project Plan for this validation.

# Release Specific Software Requirements

### Clinical Pipeline

|  |  |
| --- | --- |
| **Requirement ID** | **Description** |
| **HPS-50** | Change Variant calling pipeline wrapper to Bpipe from Perl. |
| **HPS-51** | Modify loader to deal with Torrent 5.4 Database Changes. |
| **HPS-52** | Change variant calling pipeline to use Torrent Variant Caller (TVC) 5.4. |
| **HPS-53** | Change value of filter\_unusal\_predictions parameter for TVC in variant calling pipeline. The setting for the filter\_unusual\_predictions parameter will be set to 0.3. |
| **HPS-54** | Modify the hotspot data loader so that the variant allele frequency cutoff threshold for non-control samples is greater than or equal to 1%. |

### Clinical Dashboard

|  |  |
| --- | --- |
| **Requirement ID** | **Description** |
| **HPS-47** | Add a "Director Override (DO)" tier to the variant quality control page. Variants that are assigned to this tier will be included in the "Significant Genomic Alterations" section in the report. In addition a new section titled "Other Significant Findings" will be placed after the tier 2 section and before the VUS section and will include all variants in the DO tier. |
| **HPS-49** | Remove the "Special Considerations" label from above report level comment. This means the report level comment should now directly follow the header "Interpretation" |
| **HPS-55** | Add an allele frequency filter text entry box to the Variant QC page in the dashboard. Entering a number into the text box will result in all variants for that sample with allele frequency below that number being hidden from view. The default for this filter will be empty, however the default should be able to be changed in future versions of the dashboard. All variants for a sample, even if they are hidden, must still have a status set besides pending for the sample to be able to move on to the next step in the workflow. |

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# APPROVAL

Signing this protocol indicates that the contents of this document have been reviewed and correspond to the approved validation/testing plan:

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Business Owner/Designee Date

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dir of Bioinformatics/Designee Date

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quality Assurance Date

**Approved By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Clinical Lab Director/Designee Date

# VERSION HISTORY:

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| --- | --- | --- | --- |
| **Date** | **Version** | **Description of Document Updates** | **Author** |
| 09/25/2017 | 1.0 | Initial Release | Jonathan Keeling |
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