Developing a controlled workflow for clinical studies to collect pathologist annotations

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Abstract

We are reviewing the results of a pilot study into pathologist-annotated data sets to make improvements to the data-collection process for a future pivotal study. Data collection in the pilot study showed that participants incorrectly completed steps. We outline the common mistakes participants made, their causes, and how these errors are harmful to the integrity of the project. By making changes to the data-collection platform caMicroscope, we are also able to promote a more efficient workflow. We present these improvements with an explanation of how they improve data quality and efficiency.

caMicroscope

- Web accessible image viewer
- Open-source
- Platform for uploading, marking and annotating biomedical slides

Figure 1

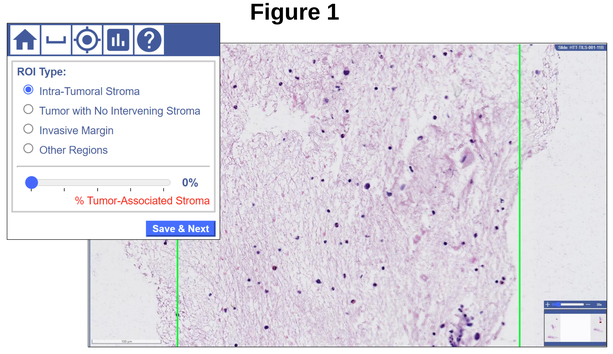

Figure 1: The viewer (right) when annotating images on caMicroscope. The green box indicates the region of interest being evaluated. Tools (left) for annotating the image are available in the viewer.

- caMicroscope was used in a pilot study to collect pathologist data
- Improvements to the clinical workflow must be made ahead of future studies

Clinical Workflow

Using caMicroscope to collect quality pathologist-annotated data sets requires a strong workflow. The pilot study workflow is shown below (Fig. 2).

Figure 2

Figure 2: Workflow stages for collecting pathologist data using caMicroscope. The focus of this work is on the “Data Collection” (red outline) portion of the workflow, but improvements were made to other stages as well.

Improvement Workflow

The following are the main tools used for making changes to the caMicroscope platform:

- SmartGit: Version control software that allows collaborative development and code archiving
- Visual Studio Code: Source code editor
- Docker Desktop: Creates a client/server environment locally to use for development

Figure 3a

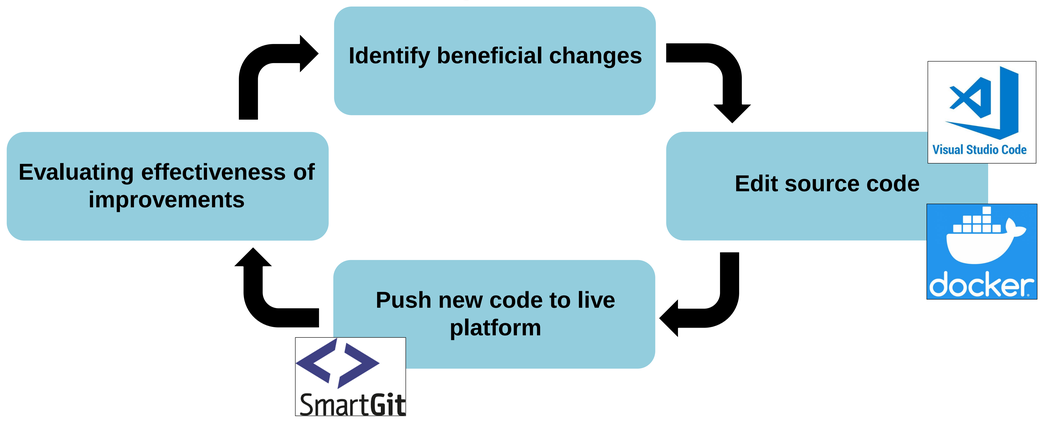

Figure 3a: Workflow for making improvements to caMicroscope. Workflow consists of identifying beneficial changes to the clinical workflow, making those changes by editing the source code using Visual Studo Code and Docker Desktop, pushing the changes to the live platform using SmartGit, and observing the effectiveness of the improvements. From here the process can repeat to continue to make improvements.

A future change to this workflow will involve precisionFDA, a community-based platform for developing tools, standards and approaches for FDA-regulated products. As the platform continues to be updated, caMicroscope will transition to being hosted on the platform.

Example: Registration and Exit Surveys

Participants in the pilot study were asked to complete registration and exit surveys to collect key information about their qualifications. The study revealed multiple improvements to the questions participants were asked such as the following:

- Requiring answers to questions before participants proceed
- Removing the wording “board-certified” to avoid confusing international participants
- Including a question to collect a participant's specialization

Figure 4

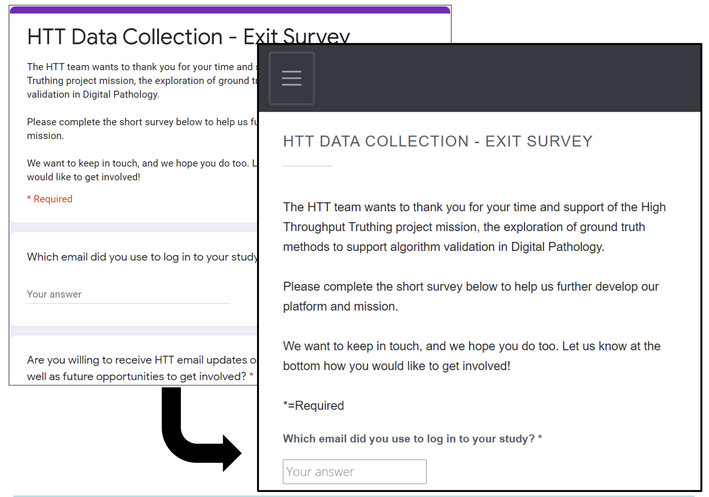

Figure 4: Original and new exit surveys. The original survey (left) was hosted on Google Forms and the new survey (right) is hosted on caMicroscope. The result is that participants are kept within one platform, participants are encouraged to complete the survey, improved security and fewer access issues due to network security.

Conclusion

Complete:

- ✓ Identified improvements that can be made to clinical workflow
- ✓ Established efficient improvement workflow
- ✓ Improved key surveys within the data collection stage

Future Improvements/Goals:

- **To-Do:** Provide task list for participants to follow when annotating
- **To-Do:** Update data retrieval to reflect data collection changes
- **NEED**: precisionFDA updates to allow for hosting caMicroscope on the platform

References:

- caMicroscope Landing Page: https://bit.ly/3iN0KqQ
- eeDAP NCI Hub: https://bit.ly/2WnSAO1
- Personal ORCID: https://bit.ly/3x641Xa