

PP19: Programming Development and Validation Tracking Application



Introduction

Problem Statement

- Need to track program development, validation and review of datasets and tables for Clinical Study Reports
- Multiple Excel spreadsheets used in multiple directories
- Excel files can become corrupted with many users, users may be locked out or can be deleted or overwritten

Solution

- Develop a Programming and Statistics Review Tracking Application (ITrack)

Return on Investment

- Easier tracking in one location
- Information is databased providing accessibility and reporting while preventing previous issues
- Ensures all processes are completed

Development and Implementation Process

Prerequisites

- Define application specifications including tracking features such as programming tasks, review comments and reporting needs
- Identify vendor to develop system
- Identify UAT team and a variety of test cases (projects)

1. Review specifications with the vendor and have vendor develop system

3. Vendor makes updates and UAT is performed again

5. Set-up Email address for user questions and suggestions and train Subject Matter experts to help users

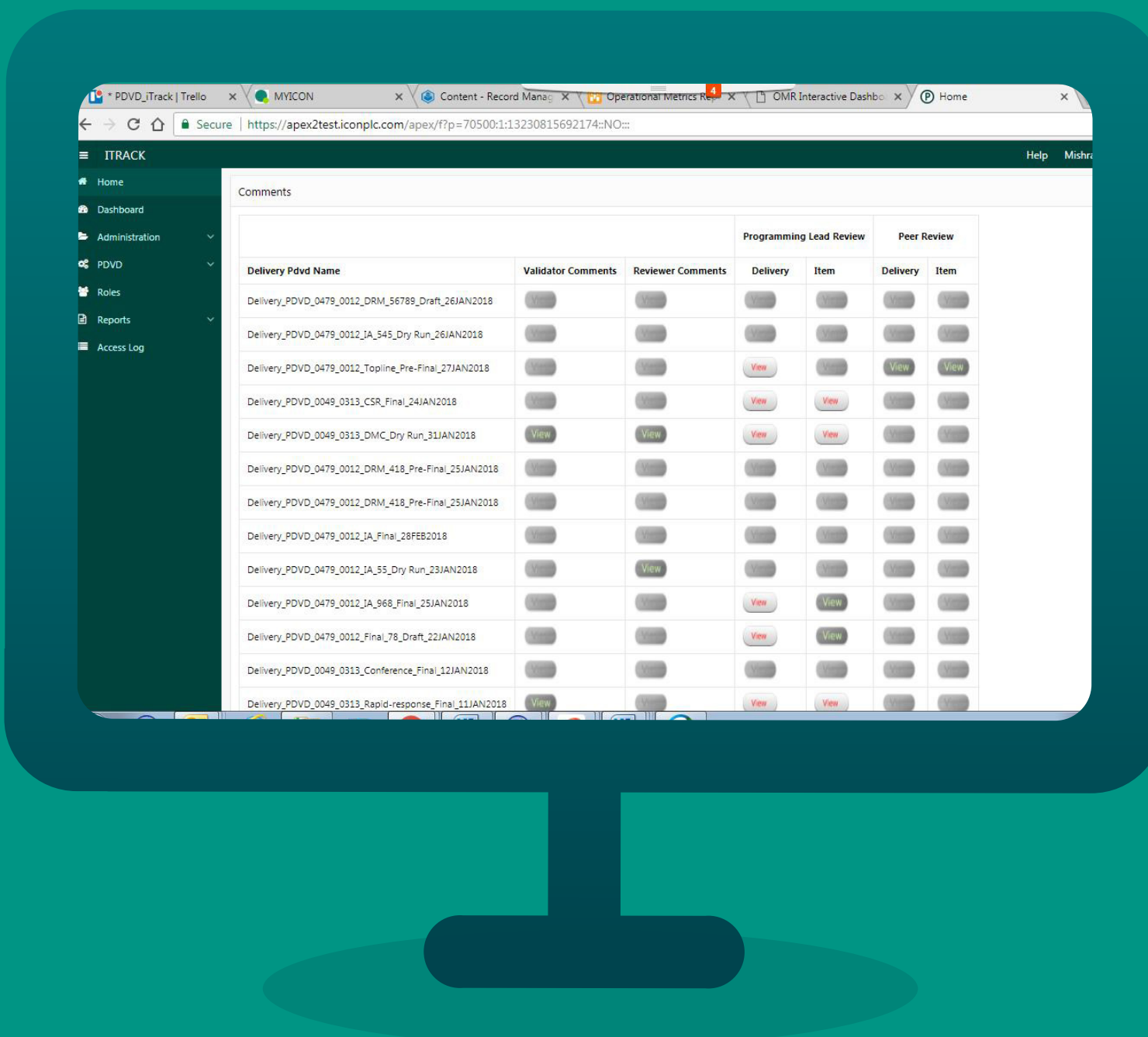
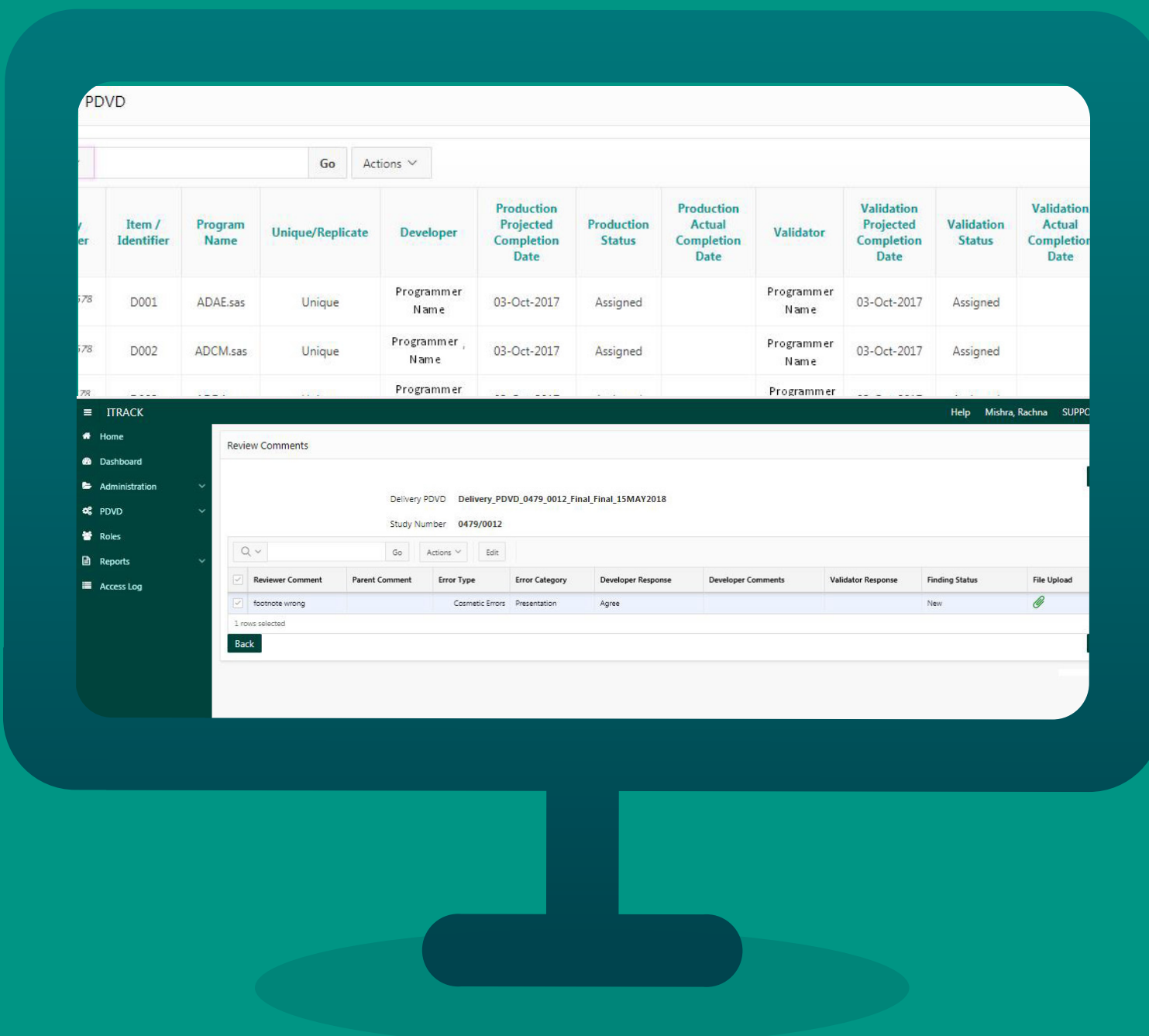
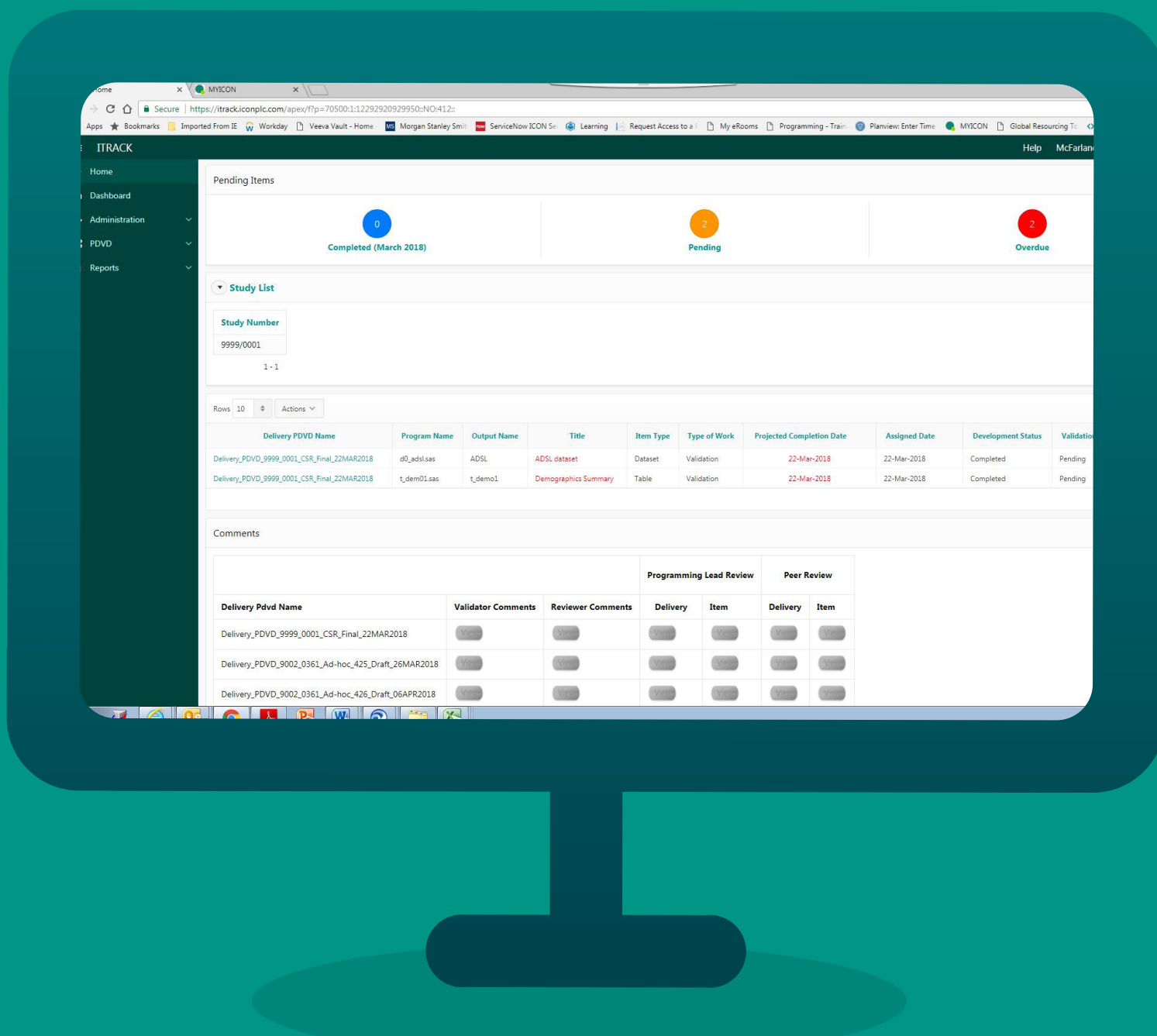
7. Review user suggestions and prioritize implementation to improve system regularly

2. Perform User Acceptance Testing and provide feedback to the Vendor

4. Pilot system on a few studies and then Roll-out training and system to department

6. Request user feedback including management

Examples of ITrack Dashboard, Programming and Validation tracking, Comments tracking and Reporting



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