

## **Root Cause Analysis Using Pinnacle 21 Validation Reports: How to Improve End-to-End Programming Process**

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### **ABSTRACT**

As reviewers adjudicate Pinnacle 21 validation reports to address the quality of submission activities, further analysis can uncover underlying process-related issues which cause those findings in the first place. Even a single Pinnacle 21 validation report can identify underlying shortcomings. However, if you are a large pharmaceutical company or have access to a large number of Pinnacle 21 validation reports, it can help you analyze various trends and improve all aspects of the current programming process. In this paper, we will discuss how to analyze Pinnacle 21 validation reports, categorize findings in various buckets such as Data Collection, SDTM Process, ADaM Process, CRO Management, e-Submission Process, Internal Stakeholder Management, External Stakeholder Management, Training, and subsequently how to use root cause analysis to find and address end-to-end programming process improvement.

### **INTRODUCTION**

### **HOW TO PREPARE FOR META-ANALYSIS OF PINNACLE 21 VALIDATION REPORTS**

### **ROOT CAUSE ANALYSIS – DATA COLLECTION**

### **ROOT CAUSE ANALYSIS – SDTM PROCESS**

### **ROOT CAUSE ANALYSIS – ADAM PROCESS**

### **ROOT CAUSE ANALYSIS- CROMANAGEMENT**

### **ROOT CAUSE ANALYSIS – E-SUBMISSION PROCESS**

### **ROOT CAUSE ANALYSIS – INTERNAL STAKEHOLDER MANAGEMENT**

### **ROOT CAUSE ANALYSIS – EXTERNAL STAKEHOLDER MANAGEMENT**

## CONCLUSION