# Considerations for Quality Control Monitoring of Machine Learning Models in Clinical Practice

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Submitted to: JMIR Medical Informatics
on: July 07, 2023

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## *Abstract*

**Background:** Integrating machine learning models into clinical practice presents a challenge of maintaining their efficacy over time. While the existing literature offers valuable strategies for detecting declining model performance, there is a need to document the broader challenges and solutions associated with real-world development and integration of model monitoring solutions.

**Objective:** This work details the development and utilization of a platform for monitoring the performance of a production-level machine learning model operating in Mayo Clinic. The aim of this work is to provide a series of considerations and guidelines necessary for integrating such a platform into a team's technical infrastructure and workflow. We document our experiences with this integration process and discuss the broader challenges encountered with real-world implementation and maintenance. Source code for the platform is also included.

**Methods:** Our monitoring platform was built as an R shiny application; developed and implemented over the course of 6 months. The platform has been utilized and maintained for 2 years and is still in use as of July 2023.

**Results:** The considerations necessary for the implementation of the monitoring platform center around four pillars: Feasibility – what resources can be utilized for platform development?; Design – through what statistics or models will the model be monitored, and how will these results be efficiently displayed to the end-user?; Implementation – how will this platform be built and where will it exist within the IT ecosystem?; and Policy – based on monitoring feedback, when and what actions will be taken to fix problems and how will these problems be translated to clinical staff?

**Conclusions:** While much of the literature surrounding machine learning performance monitoring emphasizes methodological approaches for capturing changes in performance, there remain a battery of other challenges and considerations that must be addressed for successful real-world implementation.

(JMIR Preprints 07/07/2023:50437)
DOI: https://doi.org/10.2196/preprints.50437

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## Original Manuscript

# Considerations for Quality Control Monitoring of Machine Learning Models in Clinical Practice

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Keywords: Artificial Intelligence, Machine Learning, Implementation Science, Quality Control, Monitoring, Patient Safety

## Abstract

Integrating machine learning models into clinical practice presents a challenge of maintaining their efficacy over time. While the existing literature offers valuable strategies for detecting declining model performance, there is a need to document the broader challenges and solutions associated with real- world development and integration of model monitoring solutions. This work details the development and utilization of a platform for monitoring the performance of a production-level machine learning model operating in Mayo Clinic. The aim of this work is to provide a series of considerations and guidelines necessary for integrating such a platform into a team's technical infrastructure and workflow. We document our experiences with this integration process and discuss the broader challenges encountered with real-world implementation and maintenance. Source code for the platform is also included. Our monitoring platform was built as an R shiny application; developed and implemented over the course of 6 months. The platform has been utilized and maintained for 2 years and is still in use as of July 2023. The considerations necessary for the implementation of the monitoring platform center around four pillars: Feasibility – what resources can be utilized for platform development?; Design – through what statistics or models will the model be monitored, and how will these results be efficiently displayed to the end-user?; Implementation – how will this platform be built and where will it exist within the IT ecosystem?; and Policy – based on monitoring feedback, when and what actions will be taken to fix problems and how will these problems be translated to clinical staff? While much of the literature surrounding machine learning performance monitoring emphasizes methodological approaches for capturing changes in performance, there remain a battery of other challenges and considerations that must be addressed for successful real-world implementation.

## INTRODUCTION

As machine learning (ML) models integrate into clinical practice, ensuring their continued efficacy becomes a critical task. A pervasive limitation in ML is the inability for most models to adapt to changes in their environment over time. As a result, a model that may have performed exceptionally in its development environment can become gradually or immediately less accurate while in production [1, 2]. This problem has been well studied by the ML community, with the current literature offering invaluable methodological strategies for the detection of declining model performance and the ethical implications of such declines. [3, 4, 5, 6, 7] However, the proper choice of monitoring algorithm is only one step in the larger series of problems and considerations surrounding the sustained maintenance of these models in a real-world scenario. While some authors address the wider set of problems encountered in the long-term maintenance strategy of a deployed model, it is typically only an acknowledgment of these problems, rather than the personal experiences and solutions developed to solve them. [8, 9] As such, we aim to supplement the current literature with an alternative approach in which we provide an in-depth review of the experiences and challenges encountered when integrating our ML monitoring solution into clinical practice.

This manuscript focuses on a ML model implemented into Mayo Clinic's practice in 2018. The model, known as "Control Tower", is a fully integrated healthcare delivery model which predicts the need for inpatient palliative care through modeling palliative care consultation. The model runs automatically on all inpatients at Mayo Clinic's St. Mary's and Methodist Hospitals in Rochester, Minnesota, with patient scores monitored by the Palliative Care practice [10]. The approach was to treat the palliative care consult as a time-to-event out- come. Some of the features used are static (patient demographics, prior history), while others are time-varying or dynamic (such as labs/vitals/in-hospital events). To capture the time-varying nature of these covariates, we employed a heterogeneous Poisson process. Furthermore, it was crucial to account for non-linearity and interactions, as a result, we utilized a Gradient Boosting Machine (GBM). The model was validated through a clinical trial conducted from 2019 to 2022 to assess real world effectiveness and is still in use by the Palliative Care practice as of July 2023 [11, 12]. For a complete methodological overview of the machine learning model and validation procedure, please see [10]. The Control Tower monitoring platform was developed and implemented over the course of 6 months. The platform has been utilized and maintained for 2 years and is still in use as of July 2023.

The present manuscript provides a series of guidelines for developing and integrating ML performance monitoring into a team's workflow. Guidelines were developed from real-world experiences and challenges encountered throughout this process by a data science team at Mayo Clinic. In addition, a comprehensive overview of the developed monitoring platform is provided, as well as the accompanying source code for demonstration purposes. Overall, this manuscript serves as a primer for considerations that must be made when implementing and maintaining a model monitoring system in a clinical setting, coupled with the corresponding solutions our team employed.

## DEVELOPMENT OF THE MODEL MONITORING PLATFORM

Traditionally, guidelines are developed through expert-driven processes, such the Delphi method which seeks to provide standards through initial conceptions followed by several rounds of revisions until ultimately converging to an agreed upon set [13]. However, in emerging areas where expertise is sparse, expert-driven approaches are often costly when seeking consensus of multiple experts through multiple rounds of responses [14]. An alternative to the expert-driven approach is experience-driven methodologies which emphasize the personal experiences and observations of individuals who have directly encountered the phenomena. Normally these methodologies focus on practical knowledge through explication of the "real world". Our team opted to derive a set of guidelines based on our specific real-world experiences and the challenges faced when designing, implementing, and integrating the Control Tower monitoring platform. Our specific methodologies employed throughout this process are documented here and later generalized into a series of guidelines in the Design Considerations section.

## Establishing the Team and Responsibilities

When planning the phases of Control Tower, it was decided the role of monitoring the model would remain with the model development team. The task of monitoring was divided amongst four team members, rotating the responsibility of monitoring, monthly. This approach ensured monitoring would not significantly inhibit the bandwidth of any one team member. Monitoring responsibilities did not fall to the team member who developed the model, as their primary task in monitoring would be to retrain the model when necessary. The monitoring platform was checked biweekly: Mondays and Thursdays, to balance coverage and analyst time. The Monday check ensured immediate response to any issues that may have occurred during the previous weekend, and the

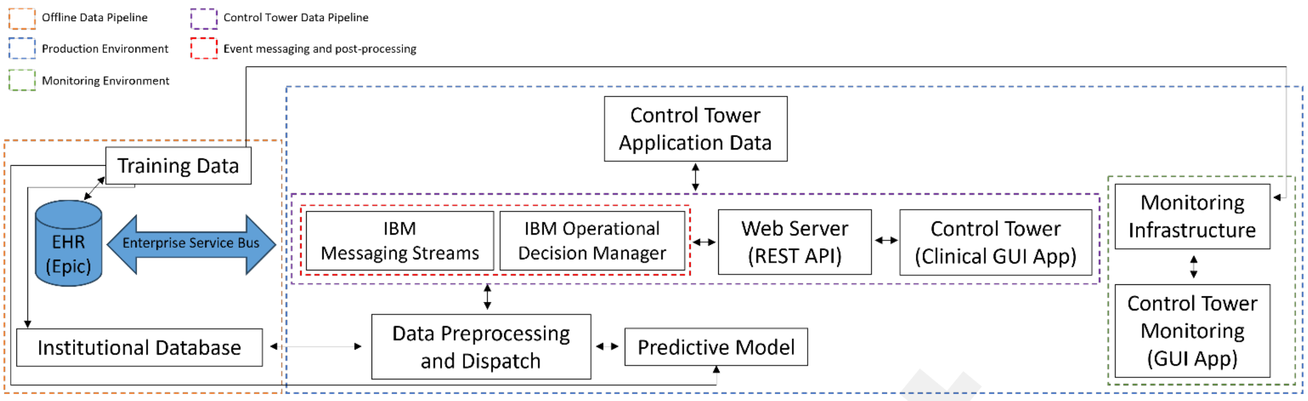

Offline Data Pipeline
Production Environment
Monitoring Environment
Control Tower Data Pipeline
Event messaging and post-processing
Training Data
EHR (Epic)
Enterprise Service Bus
Institutional Database
Control Tower Application Data
IBM Messaging Streams
IBM Operational Decision Manager
Web Server (REST API)
Control Tower (Clinical GUI App)
Monitoring Infrastructure
Control Tower Monitoring (GUI App)
Data Preprocessing and Dispatch
Predictive Model

Figure 1: System Architecture for Control Tower. For the Control Tower we have three parent processes (training, production, and monitoring) that constitute our deployment. Child processes include the orchestration of the streams, events, and the prediction pipeline, which sends scores to the GUI.

Thursday check provided enough time before the upcoming weekend to identify and resolve any errors that may have occurred during the week. Typically, a single model monitoring session would take approximately 5-10 minutes, assuming no problems were encountered.

## Development of the Model Monitoring Platform

Performance monitoring of Control Tower was accomplished through the development of an R Shiny web application comprised of data visualizations and interactive tables. The goal was to create a centralized, user- friendly platform for all team members to check model performance. The platform consisted of five different tabs addressing different types of data shift; providing multiple degrees of granularity depending on the depth of investigation required. The model utilized a set of 126 features, measured daily, and was called an average of 80,000 times per day. Daily metrics collected for performance monitoring included mean and scale covariate shifts per feature, predicted probabilities, and the number of daily predictions made by the model. The resulting data size of these collected performance monitoring metrics was trivial; however, capturing patient generated data resulted in data on the order of gigabytes per day, requiring a dedicated storage space.

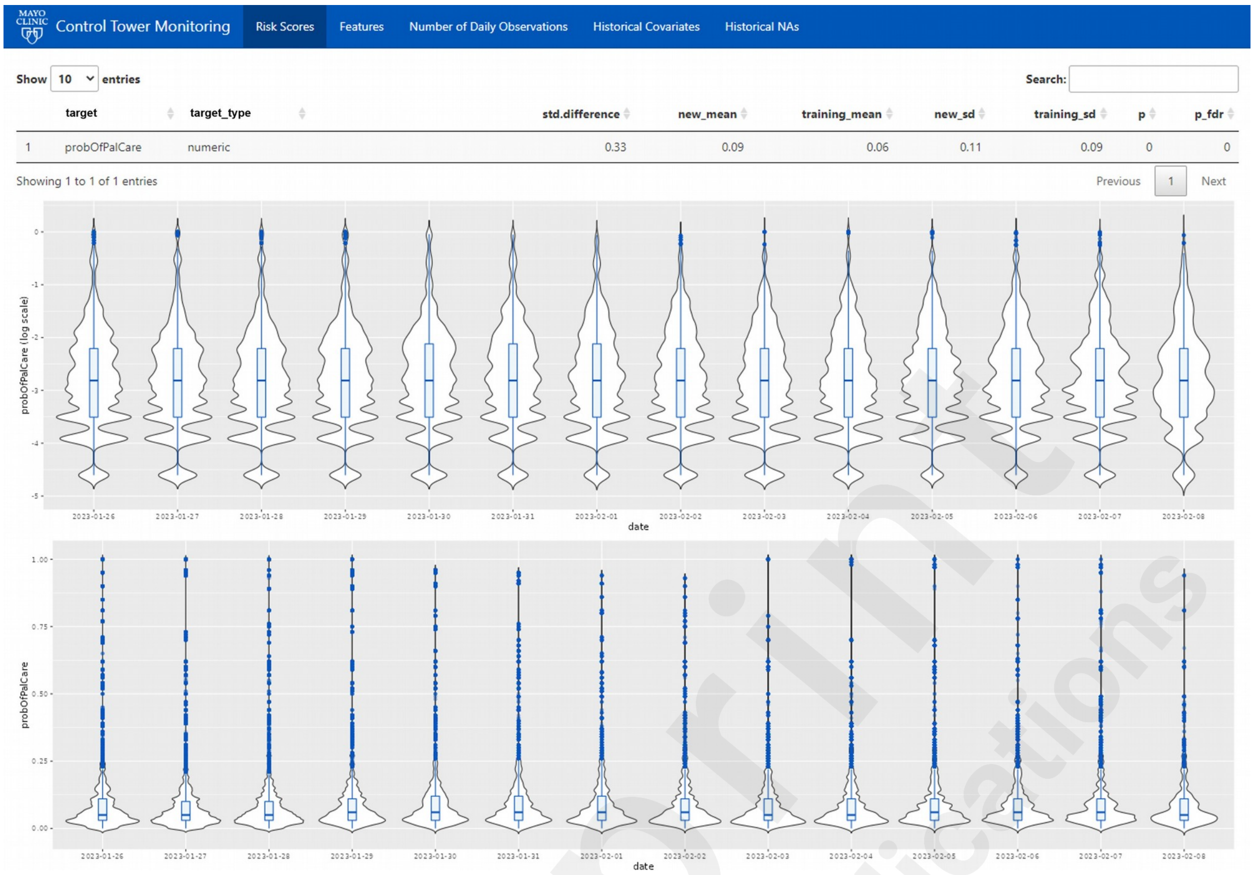
Figure 1 provides an overview of the system architecture for the Control Tower model and monitoring platform. The figure details the offline data pipeline utilized for the initial training of the Control Tower model; the components of the broader production environment and pipelines necessary for the predictive model and clinical GUI app; and finally, the components necessary for monitoring the performance of the Control Tower model. A more detailed visualization and comprehensive description of the system architecture is provided in [10]. Briefly stated, Murphree et al. outline our deployment strategy that integrates a REST API within a Docker container, enabling integration of predictive models into the Control Tower GUI. The data ingestion and preprocessing pipeline, integrated with IBM Streams and Operational Decision Manager, facilitates real-time prediction processing triggered by updates to institutional health records (HL7 messages by our EHR). The Control Tower GUI application is built with Angular.

### Monitoring Model Probabilities

In the absence of ground truth labels, predicted probabilities from the model were monitored as an alternative to evaluating model performance. The platform visualizes these predicted probabilities as distributions of daily risk scores (Fig 2). Distributions are plotted on probability and logarithmic scales, allowing for easier detection of shifts when the majority of predicted probabilities are low; considering that most patients will not be “high risk”. Historical daily distributions extend back two weeks, which is considered an optimal amount of time to notice shifts without overwhelming the user with data. Alongside these visualizations, several statistics are presented for comparing the prior two weeks data against the original training data. Means and standard deviations for the incoming and training distributions are provided, as well as the standard difference, and a p-value for the Kolmogorov-Smirnov test (K-S test) of differences between the two distributions. These statistics allow the user to detect gradual, more long-term changes that may go unnoticed when surveying two weeks of historic data. Overall, the tab shown in Fig 2. provides an overview of model predictions, allowing the user to quickly gauge whether a sudden or gradual probability shift has occurred.

## Monitoring Covariate Shift

Covariate shift was addressed in Control Tower by creating an interactive table containing all features included in the model (Fig 3). [4] The table lists feature names and type: continuous or discrete, and displays different statistical tests and plots, dependent on the feature type. To assess the impact of a feature with drift, the team included global feature importance scores from the originally trained model, in this case, the GBM's relative influence rank statistic. By providing a ranking of features based on the extent of error reduction in the model, this enables the user to triage different drifts. All other things being equal, a drifting feature with higher importance to the model than another feature, would indicate a higher priority need of a fix. Similar to the predicted probability tab, the previous two weeks of incoming data are compared to the training



| | target | target_type | std.difference | new_mean | training_mean | new_sd | training_sd | p | p_fdr |
|---|---|---|---|---|---|---|---|---|---|
| 1 | probOfPalCare | numeric | 0.33 | 0.09 | 0.06 | 0.11 | 0.09 | 0 | 0 |

Figure 2: The startup screen of the Control Tower Performance Monitoring Platform. This screen provides the user a quick overview of the model's predicted probabilities over the past two weeks. The table near the top provides several statistics comparing the distribution of predicted probabilities over the last two weeks to the predicted probabilities on the training data. The two graphs below contain a series of violin plots featuring the daily distribution of predicted probabilities. Given the predicted probabilities cluster near zero, the distributions are also displayed on the log scale for easier visual inspection.

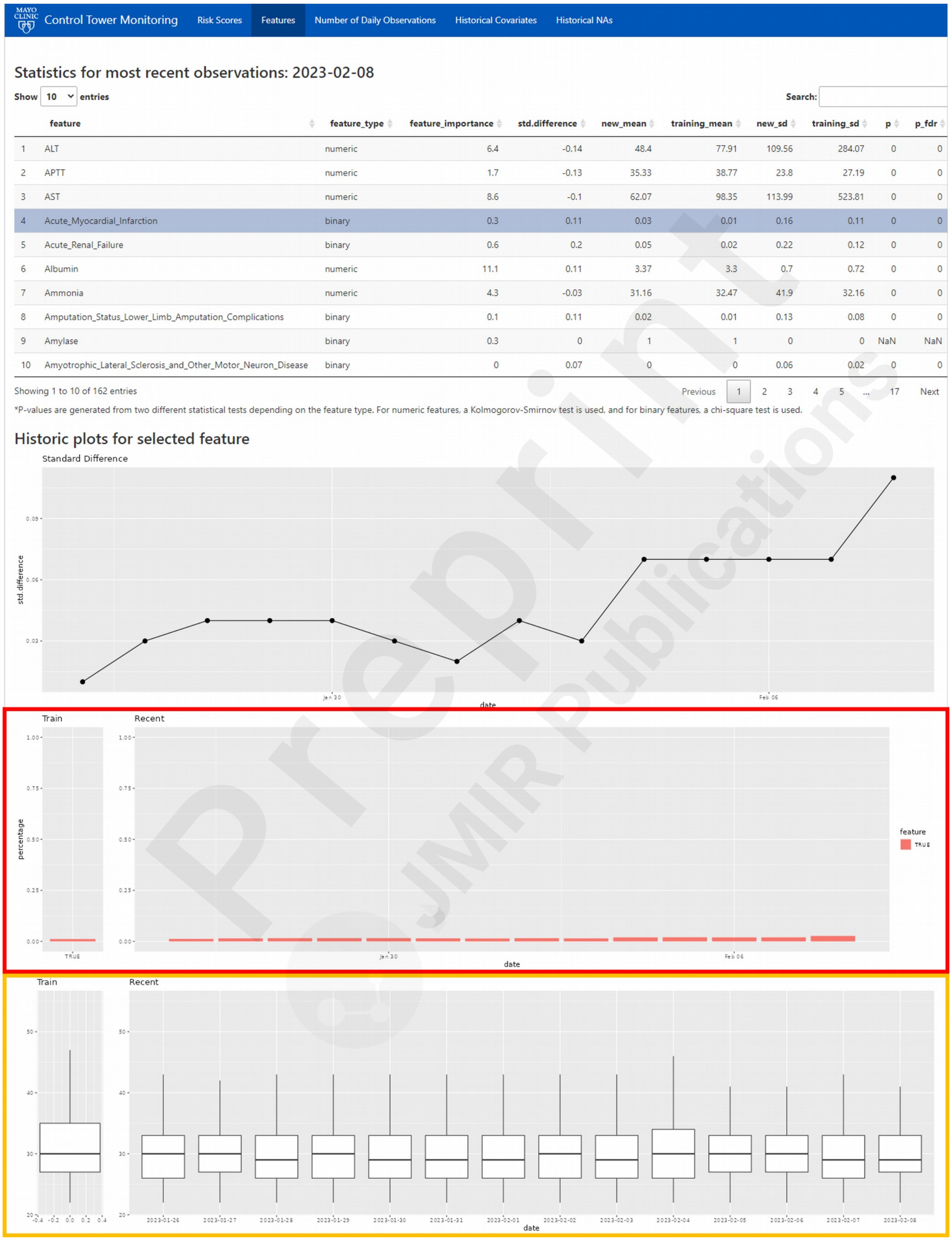
data, with standard differences, means, and standard deviations provided. To accommodate for the discrete variables present, the distributional K-S test is changed to the chi-squared test. The user can sort the table by column, allowing them to quickly pinpoint features, for example, with high standard difference. Clicking on a feature's row in the table generates two plots underneath the table. The first is a line graph visualizing the daily standard differences, spanning back two weeks. The second plot is dependent on the feature type. For continuous variables, the plot compares the feature's daily distributions over the past two weeks to the distribution of the training data, using box-plots. For discrete variables, bar plots are displayed in similar fashion indicating the percentage of patients where the discrete feature was present or "True". In tandem with the interactive table, these plots provide an efficient means of investigating a feature's historic values at a glance.

When a deeper investigation into a feature is necessary, the two week "look-back" may be insufficient. Therefore, the platform also keeps a log of the full historic feature trends, spanning back to when the model was deployed (Fig 4). Feature plots are sorted by the model's global feature importance and color-coded "green" or "red" to indicate whether the feature significantly drifted from the initial training distribution. Significance was determined via a nonparametric test developed by Capizzi and Masarotto (2013), using a p-value of 0.05. [15] A non-parametric model was used due to the fact that a moderate number of features were highly skewed making traditional methods that assume normal distributions unworkable. Each feature contains plots for the location (level) and dispersion (scale) of the distribution. Overall, this tab, in addition to serving as a historical reference, provides a simple way to spot check for gradual shifts. Finally, an additional tab (Fig 5) is provided to assess the proportion of missing values over time, utilizing the same visualizations and tests.

The final tab of the platform provides a simple line graph displaying the number of daily calls made to the model within the previous two weeks (Fig 6). Monitoring the number of daily calls can provide quick insight into whether the model is performing appropriately. For example, an abnormal number of model calls in a day, such as zero, may indicate an error in the data pipeline or model environment.

## Error Classification

Any production-level model is susceptible to various errors, and Control Tower was no exception. The majority of errors primarily revolved around technical infrastructure, particularly issues with databases being inaccessible due to nightly processing or a high influx of requests. In Table 1, a sample of encountered errors while monitoring Control Tower is presented. Although some errors were seemingly random occurrences, such as server reboots



Statistics for most recent observations: 2023-02-08

Show 10 entries Search:

| | feature | feature_type | feature_importance | std.difference | new_mean | training_mean | new_sd | training_sd | p | p_fdr |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ALT | numeric | 6.4 | -0.14 | 48.4 | 77.91 | 109.56 | 284.07 | 0 | 0 |
| 2 | APTT | numeric | 1.7 | -0.13 | 35.33 | 38.77 | 23.8 | 27.19 | 0 | 0 |
| 3 | AST | numeric | 8.6 | -0.1 | 62.07 | 98.35 | 113.99 | 523.81 | 0 | 0 |
| 4 | Acute_Myocardial_Infarction | binary | 0.3 | 0.11 | 0.03 | 0.01 | 0.16 | 0.11 | 0 | 0 |
| 5 | Acute_Renal_Failure | binary | 0.6 | 0.2 | 0.05 | 0.02 | 0.22 | 0.12 | 0 | 0 |
| 6 | Albumin | numeric | 11.1 | 0.11 | 3.37 | 3.3 | 0.7 | 0.72 | 0 | 0 |
| 7 | Ammonia | numeric | 4.3 | -0.03 | 31.16 | 32.47 | 41.9 | 32.16 | 0 | 0 |
| 8 | Amputation_Status_Lower_Limb_Amputation_Complications | binary | 0.1 | 0.11 | 0.02 | 0.01 | 0.13 | 0.08 | 0 | 0 |
| 9 | Amylase | binary | 0.3 | 0 | 1 | 1 | 0 | 0 | NaN | NaN |
| 10 | Amyotrophic_Lateral_Sclerosis_and_Other_Motor_Neuron_Disease | binary | 0 | 0.07 | 0 | 0 | 0.06 | 0.02 | 0 | 0 |

Showing 1 to 10 of 162 entries

*P-values are generated from two different statistical tests depending on the feature type. For numeric features, a Kolmogorov-Smirnov test is used, and for binary features, a chi-square test is used.

Historic plots for selected feature

Figure 3: The "Features" screen of the platform details the distributions of all features utilized by the model. The distribution of each feature based on the last two weeks of data is compared to the feature's distribution from the training data. These comparisons are provided via statistics in the table near the top which can be sorted by each statistic to quickly find features with potential drift. Clicking on a feature populates two graphs which

are displayed below the table. The first graph displays the standardized difference between the feature's distribution for that day against the distribution from the training data. Below this graph, one of two graphs will be displayed depending on whether the selected feature was binary or continuous. These graphs display the daily distributions of the feature, utilizing bar graphs for binary features (red outline) or boxplots for continuous features (yellow outline).

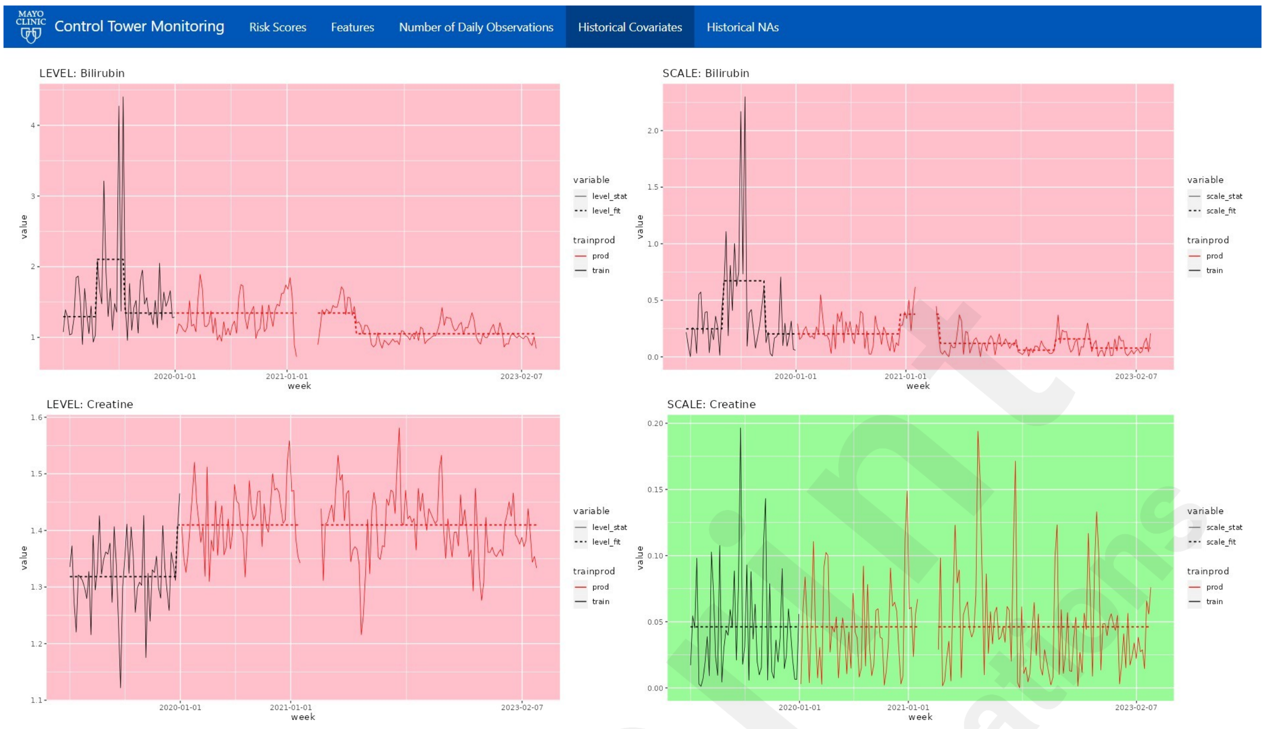


Figure 4: The "Historical Covariates" screen of the platform visualizes each feature's daily distribution, beginning with the training data and then spanning from the day the model was deployed and onward. Each feature contains plots for the location (level) and dispersion (scale) of the non-parametric distribution. Each feature's graph is color-coded "green" or "red" to indicate whether the feature's distribution has significantly drifted from the initial training distribution, with red indicating significant drift.

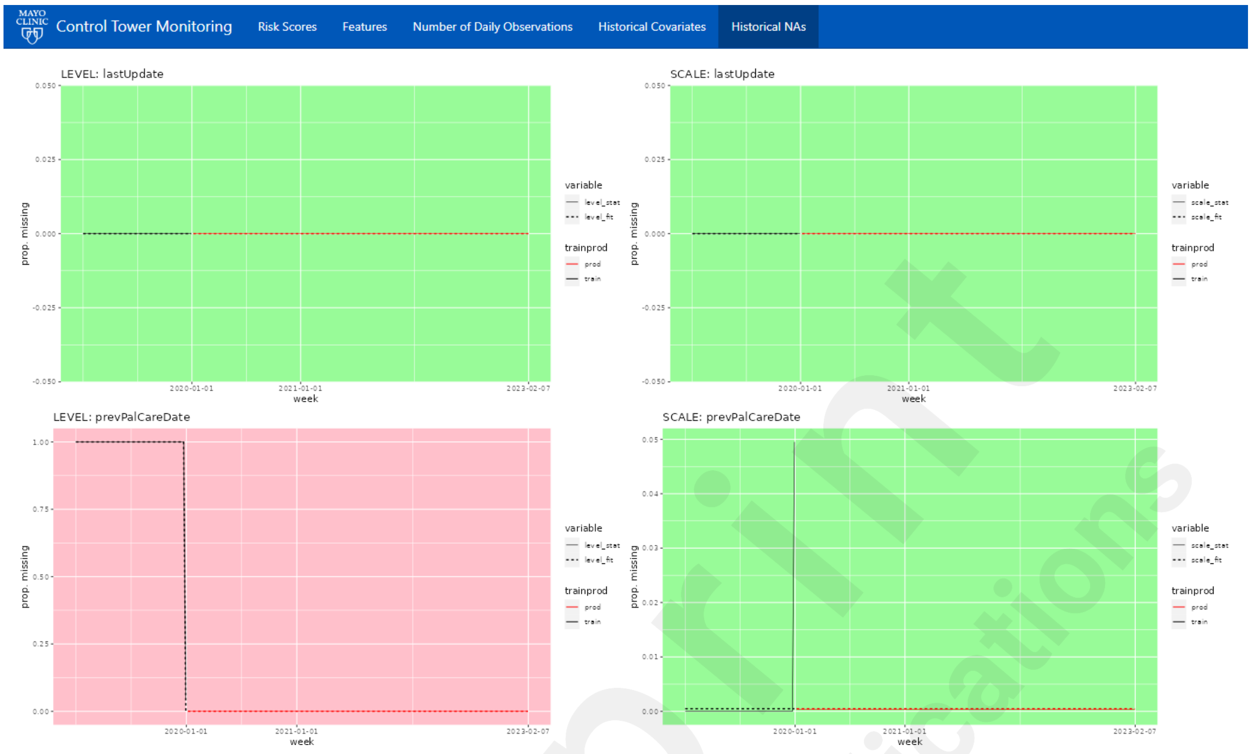


Figure 5: The “Historical NA’s” screen of the platform visualizes each feature’s historical missingness, beginning with the training data and then spanning from the day the model was deployed and onward. Each feature contains plots for the location (level) and dispersion (scale) of the non-parametric distribution. Each feature’s graph is color-coded “green” or “red” to indicate whether the feature’s missingness has significantly drifted from the initial training distribution, with red indicating significant drift.

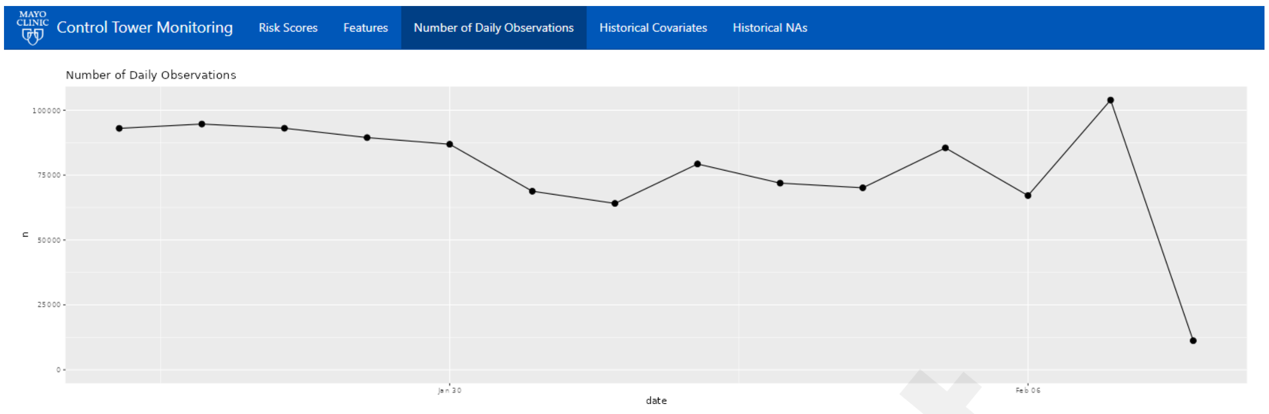


Figure 6: The "Number of Daily Observations" screen visualizes the number of model calls or predictions made each day over the past two weeks.

or expired certificates, others were more frequent and persistent. For instance, every night at specific hours, the database that supplies data to Control Tower, called Clarity, became unresponsive due to data updates. On 1/5/2022, this process was delayed and caused errors in the morning scores. Additionally, updates to our Electronic Health Record (EHR), EPIC, often resulted in Clarity being temporarily unavailable. In such cases, most issues were resolved on the same day, requiring no further action besides acknowledging the possibility of outdated or missing scores. However, a few errors necessitated intervention. On 11/7/2022, a data mart containing diagnosis codes underwent structural changes, breaking a Control Tower query. Furthermore, the team identified a covariate shift where they observed a gradual decrease in Troponin blood tests. This error was traced back to a change in lab codes used for Troponin; the clinical practice had adopted a new lab code that was not present in the training data. To address this, the error was rectified by associating the new codes with the "Troponin" feature on the platform's back-end.

### Monitoring Protocol

Actions prompted by model monitoring feedback were synthesized into a protocol to communicate model failures and down times with clinical staff. The Control Tower protocol utilized a triage system, consisting of four stages in which each stage prompts a message to the clinical team, outlined in Fig 7. The first stage (blue) was reserved for when everything was operating as expected. Stage two (Green) indicated a minor change in the layout of the tool, such as a UI change. These first two stages delivered informational prompts to the user, notifying them of the tool's status and requiring no action from the user. The third stage (yellow) indicated possible performance degradation, such as when patient scores from the model were not up to date, i.e., a day old. The day old scores can still provide evidence for action, but the clinical team may need to be cautious, as updated scores can change the patient's risk. As such, users were notified of these issues and asked to use the tool at their discretion. The last stage (red) indicated a significant error within the tool, such as a covariate completely missing from the model's input. This stage would notify staff not to use the tool until a fix was implemented.

## DESIGN CONSIDERATIONS

From our experience developing and implementing the Control Tower monitoring platform, we have derived a series of broader considerations necessary for model monitoring to serve as generalized guidelines for future implementations. Central to these guidelines arose themes of feasibility, design, implementation, and policy. While existing frameworks have proven successful in managing long-term IT infrastructure projects in health- care, machine learning models are experimental and inherently open systems, entailing costly development and maintenance. As such, they demand additional considerations due to their reliance not solely on technical data, but also on statistical and clinical assessments to identify errors. Consequently, there is no unequivocal, predetermined signal that can be provided to an IT group lacking clinical or data science expertise to detect these errors. Identifying them often necessitates the accumulation of statistical data over time. While readily available and accessible data may be used to identify some errors, others may require weeks or months of new data collection to draw inferences. Furthermore, in traditional software operations, refinements can be implemented more quickly. Responding to user feedback can often be met with bug fixes or minor feature requests. However, implementing refinements to an ML model often requires a longer development cycle, as many changes will require a complete retraining of the model or the acquisition of novel data. Such complications in model maintenance underscore the need for input from multiple teams, alongside established structures and policies, to ensure effective orchestration of model maintenance.

| Date | Error |
|---|---|
| 8/26/2019 | Multiple errors in logs. It looks like calls were during 1:45 AM to 6:00 AM. During the period 1:45 AM to 6:00 AM., all messages are failing due to Clarity Refresh. |
| 11/27/2019 | Server reboot schedule, Control Tower team was not notified of schedule leading to unexpected downtime. |
| 7/24/2020 | Increase in FHIR API for real time Observation calls leading to timeouts of model predictions. |
| 2/15/2021 | Generic FHIR API error call: “HTTP error code: 500”. |
| 4/8/2021 | Model errors after EPIC Upgrade. |
| 7/30/2021 | Troponin issues fixed causing covariate drift in model scores. |
| 9/15/2021 | Production system competed for resources requiring scale back of Control Tower scores updates. Errors created and schedule has now been updated for processing. |
| 1/5/2022 | Nightly Clarity Database delay causing morning score errors. |
| 5/16/2022 | IBM queue server certificate update causing server errors. |
| 11/7/2022 | Data mart for diagnoses codes update causing pipeline to breakdown. |
| 11/8/2022 | Issues with Clarity Database slowing down Control Tower queues. |
| 3/21/2023 | Control Tower FHIR API for real time unit changes failing for a single request, causing payload slowdown. |
| 4/5/2023 | JSON structure changing causing model error (unintended repo change). |
| 5/1/2023 | An unplanned issue impacting Enterprise API Services, who manages real time data feeds, resulting in internal server error. |

Table 1: Error Logging – A convivence sample of encountered errors while monitoring Control Tower is presented. The table was constructed through email chains of discussions between IT personnel who oversaw the Control Tower system and the data scientists who oversaw model delivery.

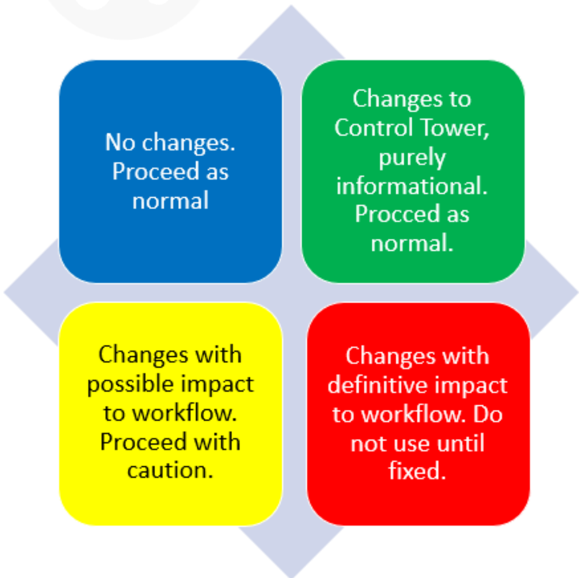

No changes. Proceed as normal
Changes to Control Tower, purely informational. Procced as normal.
Changes with possible impact to workflow. Proceed with caution.
Changes with definitive impact to workflow. Do not use until fixed.

Figure 7: Communication triage protocol for Control Tower. The protocol's stages are color-coded to signify different statuses and recommendations: blue for normal operation, green for minor layout changes, yellow for potential performance issues and red for significant errors.

## Feasibility - Are the resources to facilitate productive monitoring available?

Successful real-world implementation of models must consider the present and *future* bandwidth limitations of a team. In an ideal scenario, a team would be provided ongoing, dedicated time, or personnel to ensure the upkeep of deployed models. However, this is not always feasible, and the responsibility of maintenance competes with a team's constant stream of new projects and tasks. As such, it's important to first determine how long-term monitoring of a model (or eventually, *models*) will be integrated into the team's workflow. For example, who will check in on the model and with what frequency? If/when the model requires retraining, who will perform the retraining, and how will they be guaranteed the flexibility to shift from their current projects to accomplish this?

In addition to personnel, computational resources must also be considered for long-term monitoring. Re- garding storage requirements, the amount of data produced from monitoring depends on a variety of factors, including the model's feature set, the frequency of calls made to the model, and the number of feature and performance metrics that will be tracked. For example, a model that delivers constant, real-time feedback in a critical care setting may, in turn, require constant monitoring to ensure performance does not suddenly degrade, resulting in performance metrics and feature distribution logs needing to be generated continuously.

When assessing feasibility of long-term monitoring, an attractive option to consider is automated monitoring: developing models that detect whether a significant change has occurred in a deployed model's predictions or it's incoming data. While our team chose a 'hands-on' approach, others have found success in implementing an additional model for performance monitoring to notify the team of data shifts and, in some cases, automatically retrain the original model. [16] Ultimately, the decision to employ an automated monitoring model comes down to the type of model deployed, the bandwidth of the team, and the reliability of the data to support automatically retraining the deployed model. In any case, even an automated monitoring model will still require some human monitoring as well. Our team is currently working on an automated monitoring system for this purpose.

## Design - Deciding what and how to monitor

The design of an investigative platform to facilitate model monitoring may range from dynamic and interactive interfaces to static reports. The choice of which is dependent on feasibility factors and nuances of the particular scenario, but design should ultimately enable rapid and comprehensive assessment. Further, there are standard functionalities each platform should feature to appropriately assess long-term model performance.

Deployed models encounter performance declines through distributional and relational shifts in the underly- ing data. [17] These shifts are the crux of why post-deployment monitoring is necessary and no model is immune to them, regardless of how well it performed in its testing environment. [18] This impediment has received a wealth of attention from the ML community and has been synthesized into three types of distinct shift.

### Prior probability shift

*The distribution of the target variable $Y$ changes between the training data and incoming data, but not $P(X|Y)$.* [19] This can occur when the prevalence of a disease changes over time in the target population, however, the un- derlying factors that cause the disease, remain constant. For example, a spike in flu rates during the flu season. Prior probability shift is assessed by monitoring the distribution of the target variable over time, measuring for any sudden or gradual changes.

### Covariate shift

*Distributions of input data diverge between training data and new incoming data.* [4] Such shifts may occur in the clinical setting, for example, when diagnostic screenings are updated. This procedural change may decrease the frequency of specific labs or images, heavily relied upon by the model. Conversely, diagnostic variables which were initially infrequent, may become prevalent, resulting in many cases where the model must use variables it was unable to fully capture predictive signals from during training due to limited instances.

### Concept Drift

*The relationship between the incoming input data and target variable changes over time, drifting from the original relationship captured in the training data.* [20]. The COVID-19 pandemic provided a real-world example of concept drift, as hospital census models were affected by admissions that drastically moved towards higher-risk patients due to increases in complications from COVID-19 and decreases in hospital utilization among people with a milder spectrum of illness. [21]

### Usability

A successful UI will take into consideration the professional backgrounds of those utilizing the platform. How- ever, when the responsibilities of monitoring are handed to a different group, the new group’s level of familiarity with the model should guide design. For example, guidelines for what is acceptable variance should be estab- lished and implemented. One method for accomplishing this may be through utilizing control charts, allowing the modeling team to pre-specify a simple and visual approximation of how much drift is tolerable before action must be taken. [22]

## Implementation - How will the platform be built and sustained?

When implementing a monitoring platform, it’s necessary to consider how the back-end of the platform will process and store the necessary data elements. The efficiency of this task is critical and must accommodate the model’s scale and responsiveness. Data can amass quickly as large feature sets are monitored and the model may be called frequently to predict on many patients throughout the day. Further, the back-end must be capable of efficiently parsing, formatting, and, if necessary, compressing the data into clean data sets for the platform to analyze and visualize. For Control Tower, many of these data storage requirements were already in place for capturing and storing the necessary patient elements. This will likely be the case for many clinical scenarios, as patient data must be securely and efficiently housed. Instead, implementation efforts are more apt to center around ensuring these data elements are efficiently piped to the monitoring platform.

Utilizing a web application for model monitoring provides a dynamic interface, allowing any user with login permissions to view the real-time status of the model and surrounding data. This investigation mechanism can eliminate potential confusion which may arise from a routine generation and sharing of static technical reports, such as accidentally referencing outdated documents. When selecting a programming language to build the app, preference should be given to those languages which facilitate efficient app development. For Control Tower, R Shiny was utilized given the team’s previous experience with the package and strong background in R. The R package provides a user-friendly environment for quickly creating, testing, and publishing web applications. Similar web application tools exist across multiple programming languages including Python and Java, as such, teams are likely to find a web application package in a language they’re familiar with.

When coding the app, modular coding practices should be adopted to ensure flexibility and scalability. Such adoption promotes versatility of the app to incorporate additional statistical measures or visualizations and allows the app to be easily translated for other monitoring use cases. Leveraging modular coding practices at the onset of app development allows for future additions, revisions, and ports to be made with minimal effort. For Control Tower, modular coding practices were primarily employed to better facilitate development across multiple team members. This practice allowed for functions to be easily repurposed by other team members to avoid duplication of work and to allow the app to be easily extended to other machine learning models within Mayo.

The number of programming languages used in the data pipeline plays a significant role in shaping the development process and the overall efficiency of the monitoring. To facilitate this, minimizing the number of programming languages employed across the various tasks can streamline development and maintenance through ease of interpretability and integration. This can reduce maintenance costs and overhead by reducing interoperability concerns and decreasing the learning curve for new team members. Minimizing these ongoing costs is a necessity when considering the model will ideally be in production long-term. However, if the devel- opment team is proficient in multiple languages, leveraging the strengths of each may have its advantages, such as reducing bottlenecks in development or data transfer, while increasing the flexibility of a system. In the case of Control Tower, R, python, and shell scripts were utilized, favoring R for app development, python for data processing, and shell scripts for scheduling various model and platform tasks.

Additionally, upstream problems will inevitably manifest, therefore, implementing a notification system for these errors can proactively address disruptions, minimizing downtime of the pipeline. One method for accomplishing this is to incorporate error logging and alerts into CRON jobs, which can immediately notify the team of any failures. Such notifications are critical for model monitoring, as some errors may be undetectable to the end user, resulting in the continued use of inaccurate information. As such, it is vital for monitoring teams to identify, communicate, and resolve errors as soon as possible.

Finally, integrating regular checking of the platform into the teams workflow allowed the team to not only stay abreast of model performance, but maintain an intuitive sense of potential broader complications surrounding the model. For example, monitoring the probability distributions of the model ultimately provided the team with a sense of whether further investigations into the model would be necessary. However, investigations into distributions of the individual features allowed for potential diagnoses as to why the model may begin to degrade in performance, as well as alluded to data pipeline errors which may be present. By maintaining a sense of these wider issues, shifts in the outcome could be more easily prevented and diagnosed.

## Policy - What is the response to platform feedback?

Once the monitoring platform is deployed and available, the next stage of considerations surround how knowl- edge provided by the platform will be utilized. A set of policies must be developed to determine which actions will be taken based on monitoring feedback, addressing such questions as “At what point is a data shift signifi- cant enough to prompt retraining?” and ”How will errors be communicated with technical and clinical staff?” Generally, such a policy should cover error designation and response, when to retrain, and how to communicate failures. In addition, a well-defined policy allows for the task of monitoring to more easily be extended across various teams and roles.

### Error Designation and Response

It is essential to establish and define a process that determines when a specific degree of shift or drift in the model qualifies as an error warranting a response. The question of *’How much drift is necessary to take action?’* represents one of the more subjective aspects of model monitoring. In scenarios where multiple team members are tasked with overseeing model performance or possess limited familiarity with the model, substantial inter-rater variability becomes a concern. For example, one team member might observe a 5% shift in the distribution of a feature and consider it inconsequential, while another member might view it as a reason for immediate action. To address this variability, the Control Tower team would send email updates to other team members detailing any shifts that were noticed, this would allow for a collective discussion on whether to take action as well as allow for a convenient forum to keep all team members updated on the model’s status. Regardless of the criteria used to identify shifted covariates or outcomes, team members must communicate and establish agreement on the minimal drift threshold requiring action, while ensuring utmost priority is placed on maintaining optimal model accuracy.

Even with consensus on the magnitude of a shift, several contextual factors can influence the team’s risk tolerance towards these shifts. Significant changes may occur without sustained trends, indicating a regression to the mean. Alternatively, a dramatic shift might happen for a variable with minimal contribution to the risk score. While predefined cut-points could be considered to standardize investigations, these benchmarks may still necessitate ongoing human review and could vary for each feature, making it impractical to define for every feature in large feature sets.

Even if an error is defined with a certain level of risk in mind, there are considerations in the response to the error and the amount of time one needs to allocate for remediation. A deployed model is prone to errors from a variety of sources, ranging from data shifts to IT scheme modifications. Given the diversity of potential errors, an effective policy will include guidelines for a categorization of errors along with the appropriate responses to each. The errors encountered with Control Tower fell broadly into four categories.

1. Technical infrastructure - Database issues, expiration of certificates, and password updates often caused the pipeline to fail.
2. Explained shift - A significant data shift with an identified root cause.
3. Unexplained shift - A significant data shift with an unidentified root cause.
4. Performance loss - A decrease in the model’s performance metrics which may manifest with or without data shift.

Categorizing errors for appropriate response is crucial as it establishes a standardized knowledge base for reporting, ultimately enhancing the efficiency of troubleshooting. Categorization often leads to the discovery of similar strategies for mitigating similar error types. For instance, errors related to database refreshing or password expiration typically do not require immediate intervention, while performance losses in accuracy or calibration often necessitate retraining of the model. Appropriate categorization also offers the advantage of reducing risk tolerance while enhancing response efficiency. Having encountered an error previously, increases the likelihood of streamlining investigations, enabling the examination of lower-risk shifts or drifts.

When ongoing outcomes data is available, performance loss can be detected by looking for significant shifts across a variety of classification performance metrics including AUROC, AUPRC, calibration, subgroup differ- ences, etc. When such data is absent, as in the case of Control Tower, performance loss can only be inferred by looking for significant shifts in the distribution of predicted probabilities of the model. To supplement assessing predicted probabilities, potential performance loss may also be identified by looking for significant shifts in the features of the model. While significant shifts may occur in these features without significant shifts in the model’s output, drifts in feature distributions can signal other potential problems necessary to address. While performance loss may be resolved or mitigated through upstream pipeline errors, some instances may require the model to be retrained.

### Model Retraining

The circumstances for when to retrain a model will vary across teams and platforms, often dependent on the cost of retraining. As such, it's necessary for a platforms policy to clearly state when - and when not - to retrain. For example, many errors will not require model retraining such as simple pipeline errors or data shifts due to changes in medical coding, requiring only a small update to the pipeline. Therefore, it's important to first identify and fix any upstream errors before considering retraining. There are even instances of significant shift that do not warrant retraining. For example, one could have several shifted covariates in the model with trivial importance scores, effectively having no impact on predictive performance. From the perspective of model importance, one may bin covariates that have little impact and essentially treat them as nuisance variables.

Assuming no upstream errors are present, a model should always be retrained when significant and sustained performance loss is encountered. Defining ”significant” and ”sustained”, will be specific to each scenario, depending on the algorithm and healthcare delivery model. However, it is incumbent upon the team to define an appropriate window for performance to vary, with a lower limit triggering retraining.

It's important to note that retraining does not have to be used sparingly, assuming the bandwidth is available. When feasible, it may be good practice to routinely retrain the model with the expectation that updated data are more current with clinical practice. Such versioning of the model would allow for new features, incremental improvements, and managing technical debt. For Control Tower, versioning allowed us to spot potential bugs/fixes and investigate new features.

### Communicating with Clinical Staff

The clinical team utilizing the model's outputs must be consistently informed about the model's status due to its significance to their workflow and overall trust in the model. The model's Standard Operating Procedure (SOP) outlines how the clinical team should utilize the model and details communication protocols between IT, Data Science and the clinical users. Protocols should consist of dedicated contacts for various issues and plans for how to operate during model performance shifts and downtime.

## DISCUSSION

## Principal Findings

As ML models require consistent monitoring to ensure sustained accuracy, a series of decisions must be made for how best to integrate model monitoring within a team's workflow. Problems, considerations, and solutions that arise from this process can vary greatly depending on the setting, nature of the model, and available band- width, both from the technical team and their computational resources. While prior work has established the importance of monitoring and corresponding statistical solutions, our manuscript provides specific considera- tions and solutions derived from the real-world implementation and day-to-day utilization. [23, 24] Throughout the integration of Control Tower, our team found these considerations centered around four phases: feasibility, design, implementation, and policy; serving as a road map when planning a long-term modeling strategy.

## Experiences

Development and implementation of the platform faced several obstacles which we attribute to the inherent realities of integrating real-world applications. First, the team was unable to complete the platform by the time the associated clinical trial for the Control Tower model began recruitment. This required the team to omit crucial features from the platform, such as monitoring for concept drift. Monitoring concept drift required collecting ground truth outcomes i.e. whether patients actually received palliative care. Collecting these patient outcomes required building a separate data pipeline, which was the team's original intent, but as the team took on additional tasks, the pipeline was passed over in favor of monitoring predicted probabilities. While omitted from Control Tower, in scenarios where outcomes data are tracked, we direct the readers to literature providing a more comprehensive understanding of concept drift. [25, 26, 27]

The original intention for Control Tower was to have the model run any time patient's lab values were updated, ensuring patient's risk scores were always reflective of current data. While the model was originally deployed using this dynamic system, it, unfortunately, proved too taxing for the IT infrastructure in which it was hosted. To alleviate this problem, the model and platform were switched to running on a batch schedule, updating patient risk scores and the monitoring platform, every four hours. While this delivery schedule proved more manageable, model calls made between these four-hour updates ran the risk of using outdated patient data, potentially impacting performance. Given workload imposed by the original schedule was infeasible, however, this was considered a fair compromise. Finally, implementation of the platform occurred during the COVID-19 pandemic, which affected staffing and resulted in IT furloughs. Un- fortunately, this meant that technical infrastructure problems, which could typically be fixed by IT on the day of, instead, took up to a week to fix, resulting in prolonged downtime for the model.

Despite these challenges, there were several positive experiences to highlight. First, a significant amount of collaboration occurred within the data science team in order to have the monitoring platform in a usable

state by the time of the model's clinical trial. This required analysts to tend to a variety of tasks, often on a moment's notice. Following deployment, there was also sufficient bandwidth from the team members to continue monitoring the platform as they took on additional projects. Second, IT furloughs as a result of the pandemic were resolved within 6 months, allowing routine technical infrastructure issues to once again be resolved day of, resulting in less model downtime. Finally, the model's predicted probabilities remained, for the most part, consistent, making for a stable tool throughout the documented 2 years of utilization. Utilizing a simple linear regression model, we examined the relationship between daily predicted probabilities (dependent variable) and time since deployment (independent variable), observing a slope of 0.005 at a P-value < .001, suggesting a statistically significant, but functionally small trend, with the mean probability increasing .005% each day.

## Limitations

Despite a thorough detailing of our experiences, it's important to note that this manuscript covers only a single implementation. While we've recounted the challenges and considerations necessary for Control Tower, this is not an exhaustive list, and other teams and platforms may encounter challenges foreign to ours.

## Future Considerations

The Control Tower platform allowed our team to successfully monitor performance and maintain our deployed model for two years. Moving forward, our team is planning to automate parts of this task, for example, by implementing an automated email notification system, notifying the team when the number of model calls, predicted probabilities, and incoming data streams shift beyond their respective significance thresholds. While this modification is not intended to outright replace manually checking the platform, it will allow the team to check the platform at a lesser frequency. This system will serve as a placeholder while the team develops a new model to monitoring the performance of Control Tower, leveraging supervised learning to detect shifts in the probability and multivariate covariate distributions. [28, 29]

The team also considered an online or continuous learning model to automatically address data drift. In continuous learning, the algorithm would update its predictions as new data comes in and alleviates the need to manually retrain the data. [30] Although appealing, a system that is in this sense automated, would require more policy and would bring with it a number of issues. First, there are several cost and computing issues that could make an implementation difficult, as entire systems would need to know when to train and to do it without interrupting the current pipeline, as well as a validation step to ensure sustained, if not improved, accuracy. Second, the algorithm must remain trustworthy for clinicians. Did the algorithm *unlearn* anything important? Did it learn anything irrelevant or incorrectly? As an example, if a covariate shift occurred due to a missing lab code, resulting in increasingly missing values of that lab, we would not want the model to learn a new relationship with the missingness, instead we would make an update to the data pipeline to resolve the missingness. Finally, all continuous learning models require ready access to the gold standard outcome which might not be feasible in all cases.

## Conclusions

Once an ML model has been successfully developed and deployed, it must be continuously monitored to ensure its efficacy amidst an ever-evolving practice and stream of patients. While a variety of methods have been proposed to statistically monitor the performance of models, this is only one factor to consider when implementing a long- term modeling strategy. By disseminating the broader experiences of integrating ML monitoring platforms into clinical practice, readers will be better equipped for the considerations and challenges encountered during their own implementations.

## ACKNOWLEDGEMENTS

The research reported in this paper was supported by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health under award number R01EB019403. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

## CONFLICT OF INTEREST STATEMENT

None declared.

## ABBREVIATIONS

ML: Machine learning

EHR: Electronic health record

## DATA AVAILABILITY

The data used in this analysis were aggregated from operational clinical sources with the approval of the Mayo Clinic Institutional Review Board (MC IRB) and due to concerns of patient identification, are not posted publicly. The data may be shared on reasonable request to the corresponding author, but note, such requests may need separate approval by the MC IRB.

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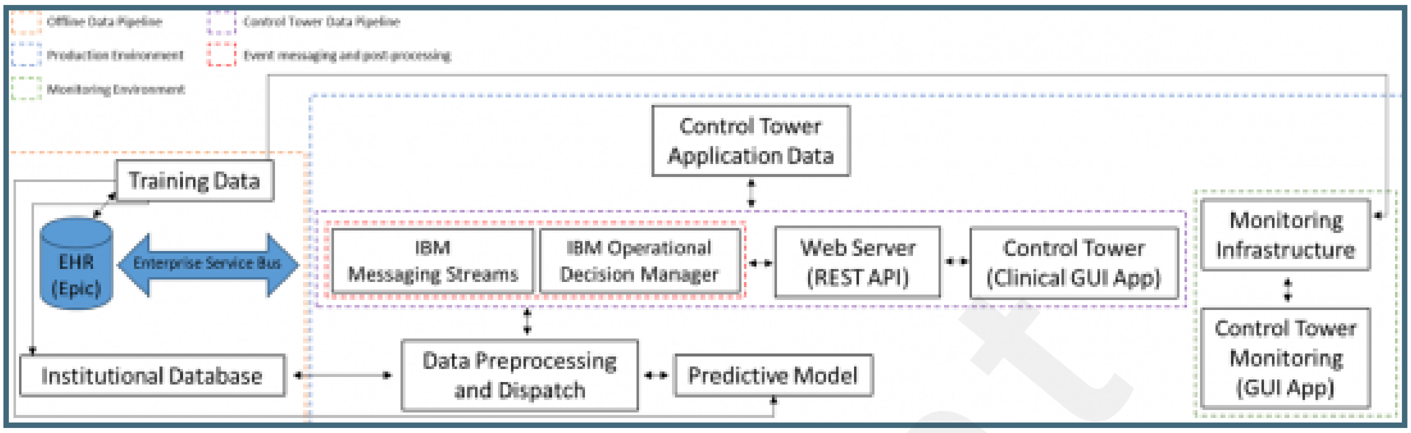
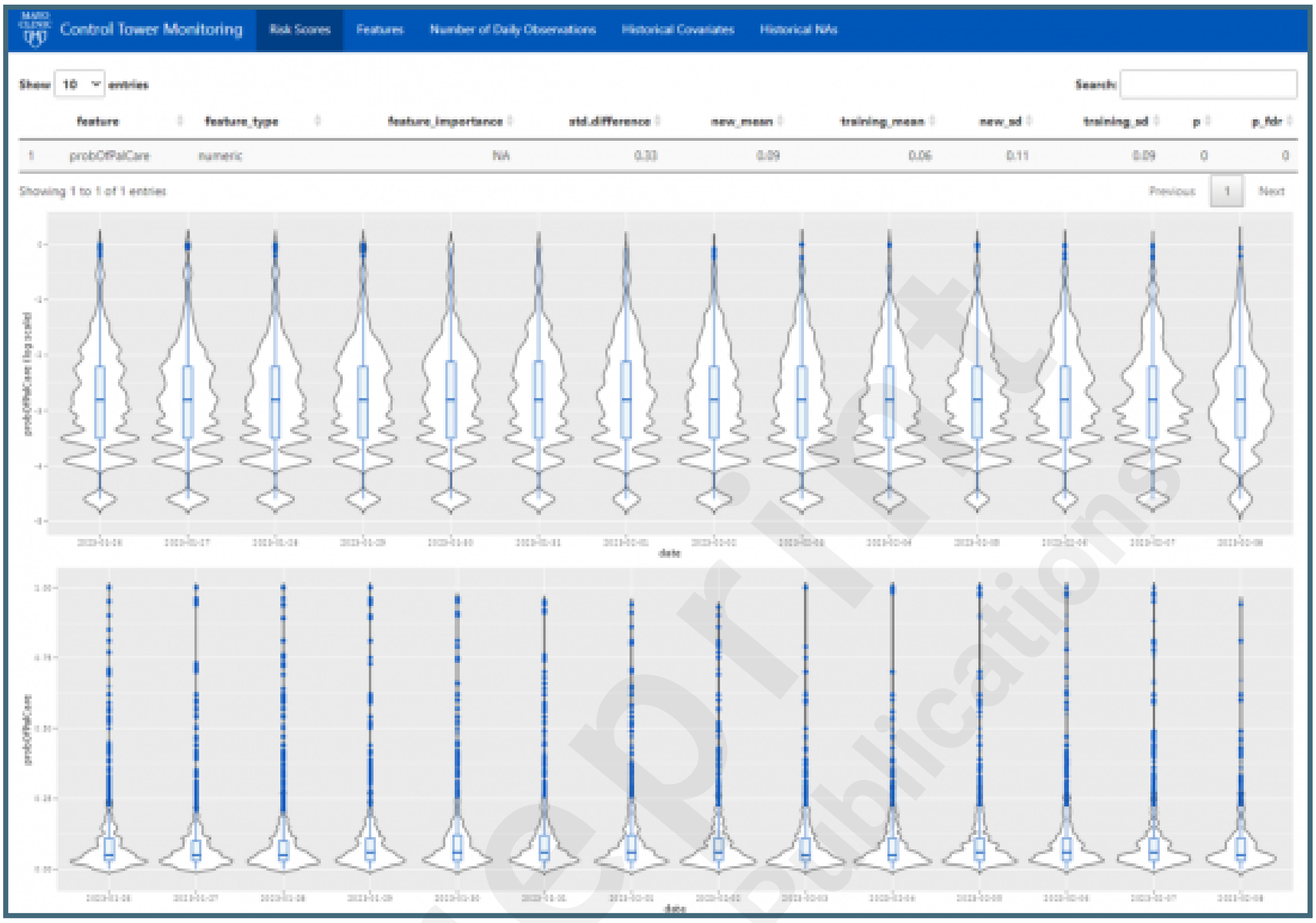
## Supplementary Files

## Figures

System Architecture for Control Tower.


Offline Data Pipeline
Control Tower Data Pipeline
Production Environment
Event messaging and post processing
Monitoring Environment
Control Tower Application Data
Training Data
EHR (Epic)
Enterprise Service Bus
IBM Messaging Streams
IBM Operational Decision Manager
Web Server (REST API)
Control Tower (Clinical GUI App)
Monitoring Infrastructure
Control Tower Monitoring (GUI App)
Institutional Database
Data Preprocessing and Dispatch
Predictive Model

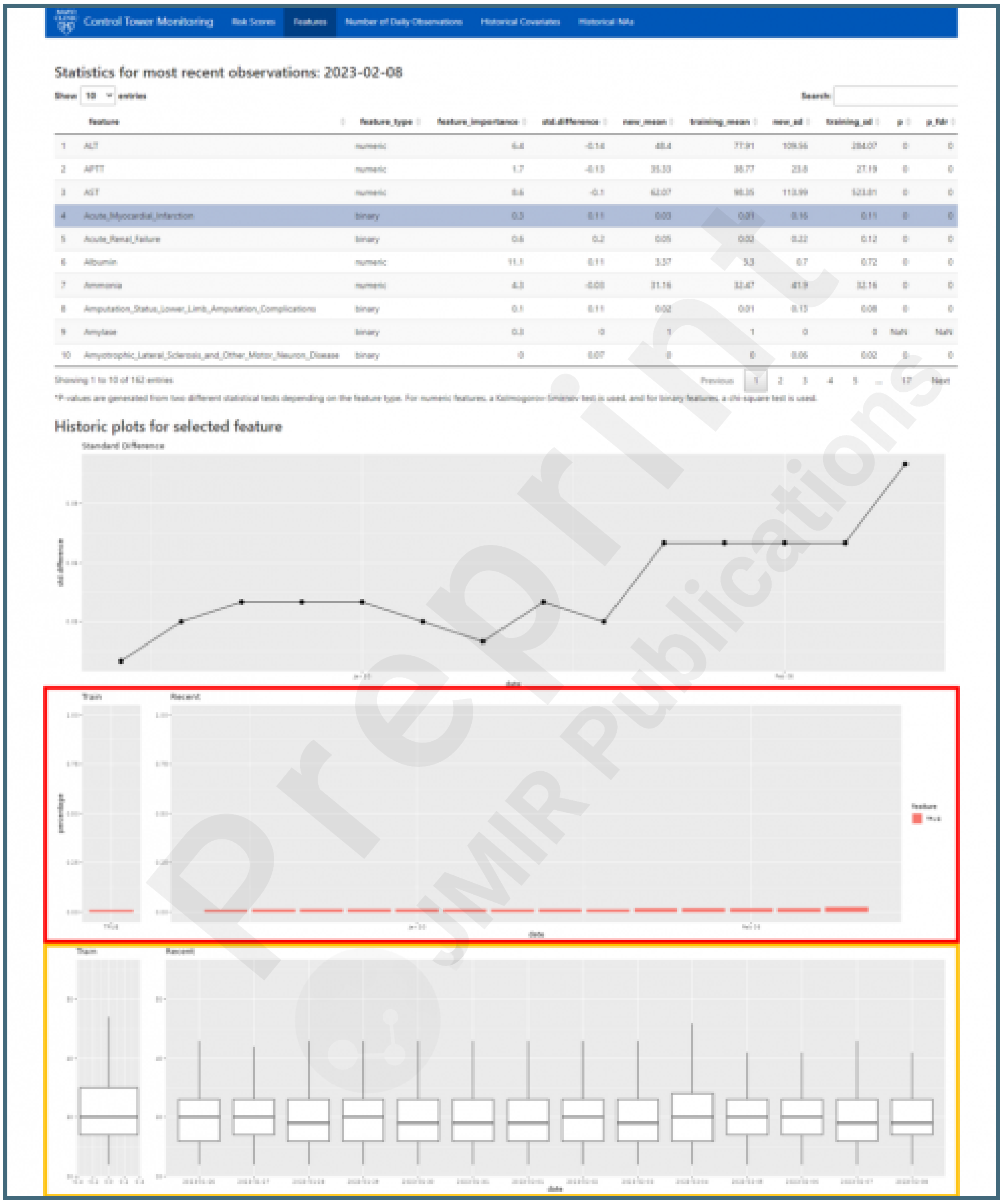
Daily risk scores.



| | feature | feature_type | feature_importance | std.difference | new_mean | training_mean | new_sd | training_sd | p | p_fdr |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | probOfPalCare | numeric | NA | 0.33 | 0.09 | 0.06 | 0.11 | 0.09 | 0 | 0 |

Showing 1 to 1 of 1 entries

Covariates. The red outline displays the visualization used when a binary feature is selected, while the yellow outline displays the visualization used when a continuous feature is selected.



Statistics for most recent observations: 2023-02-08

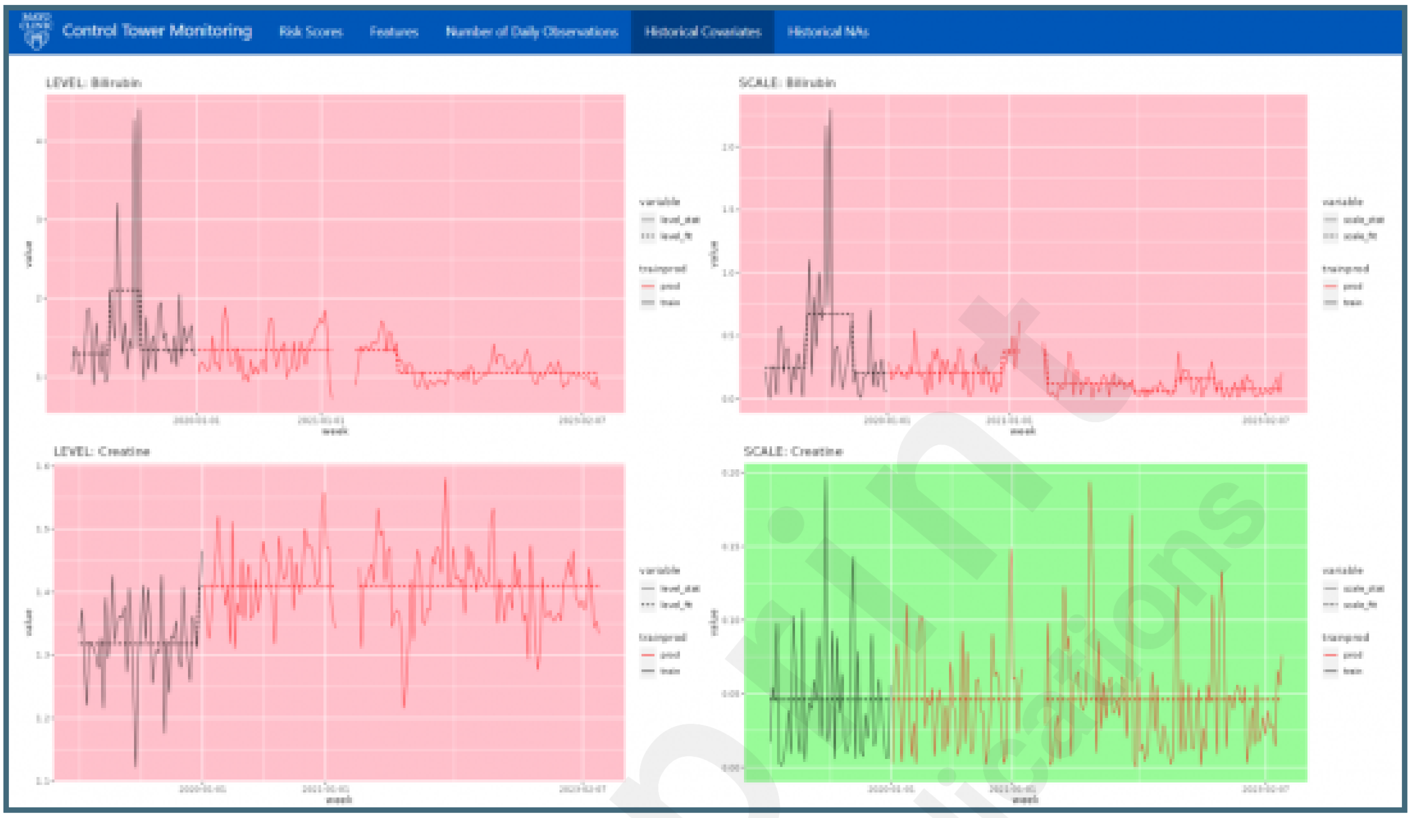
| | feature | feature_type | feature_importance | std.difference | new_mean | training_mean | new_sd | training_sd | p | p_fdr |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ALT | numeric | 6.4 | -0.14 | 48.4 | 77.91 | 109.56 | 284.07 | 0 | 0 |
| 2 | APTT | numeric | 1.7 | -0.13 | 35.33 | 38.77 | 23.8 | 27.19 | 0 | 0 |
| 3 | AST | numeric | 0.6 | -0.1 | 62.07 | 98.35 | 113.99 | 523.81 | 0 | 0 |
| 4 | Acute_Myocardial_Infarction | binary | 0.3 | 0.11 | 0.03 | 0.01 | 0.16 | 0.11 | 0 | 0 |
| 5 | Acute_Renal_Failure | binary | 0.6 | 0.2 | 0.05 | 0.02 | 0.22 | 0.12 | 0 | 0 |
| 6 | Albumin | numeric | 11.1 | 0.11 | 3.37 | 3.3 | 0.7 | 0.72 | 0 | 0 |
| 7 | Ammonia | numeric | 4.3 | -0.03 | 31.16 | 32.47 | 41.9 | 32.16 | 0 | 0 |
| 8 | Amputation_Status_Lower_Limb_Amputation_Complications | binary | 0.1 | 0.11 | 0.02 | 0.01 | 0.15 | 0.08 | 0 | 0 |
| 9 | Amylase | binary | 0.3 | 0 | 1 | 1 | 0 | 0 | NaN | NaN |
| 10 | Amyotrophic_Lateral_Sclerosis_and_Other_Motor_Neuron_Disease | binary | 0 | 0.07 | 0 | 0 | 0.06 | 0.02 | 0 | 0 |

Showing 1 to 10 of 162 entries

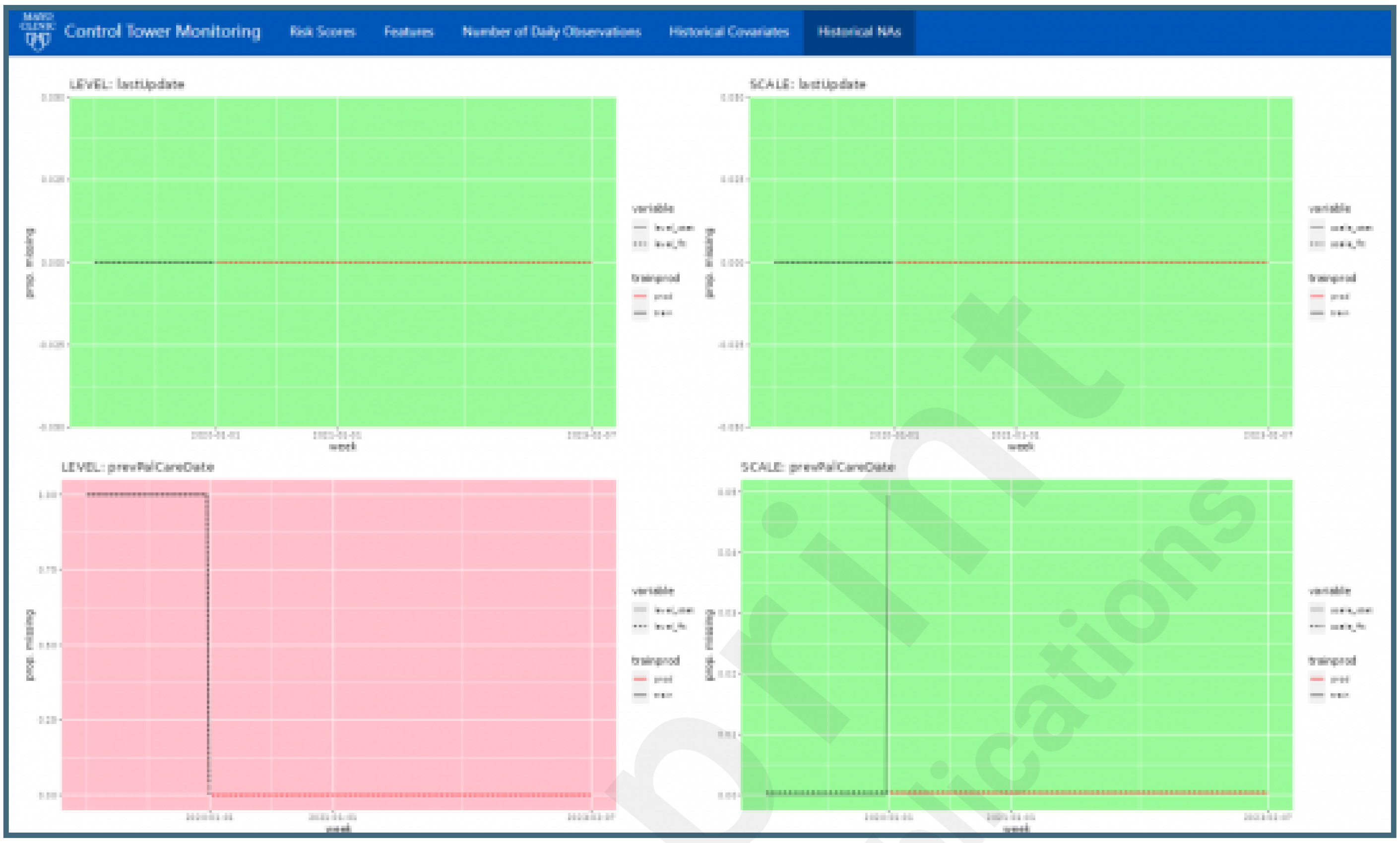
*P-values are generated from two different statistical tests depending on the feature type. For numeric features, a Kolmogorov-Smirnov test is used, and for binary features, a chi-square test is used.

Historic plots for selected feature

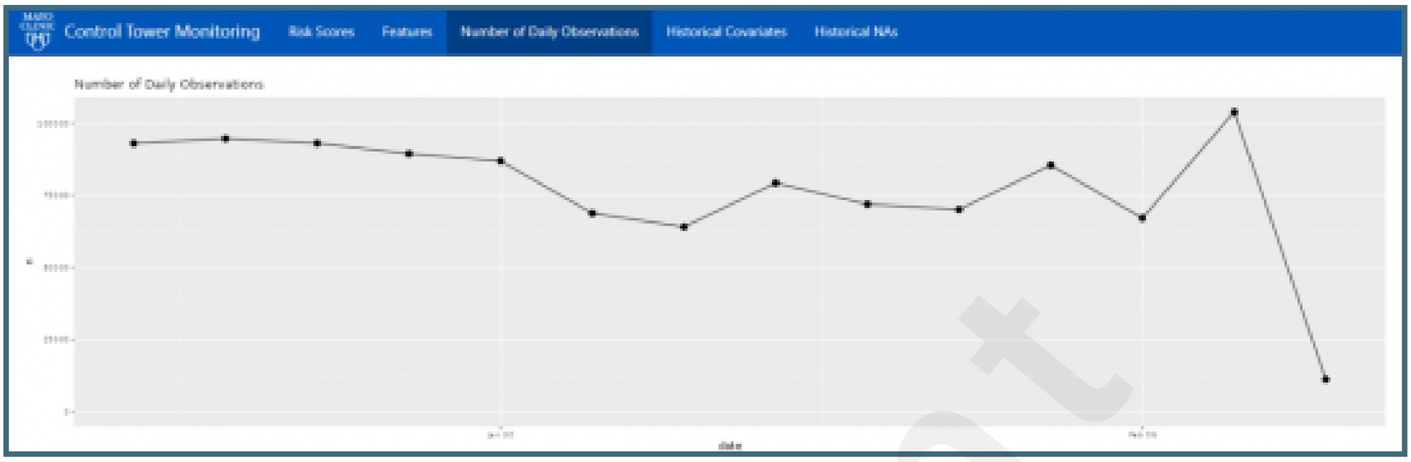
Historical covariates.



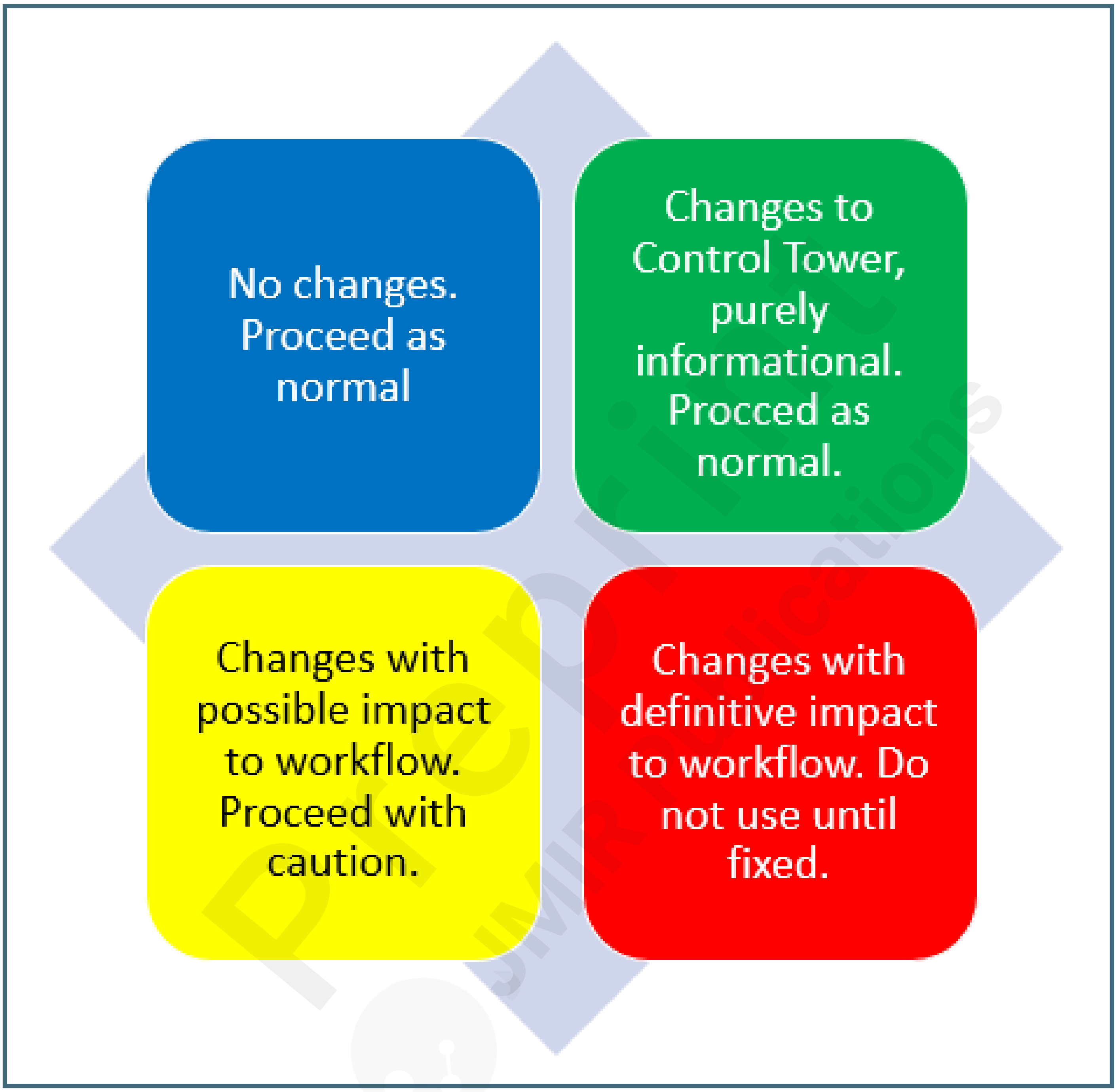
Historical missingness.



Number of daily observations.



Communication triage protocol for Control Tower.


No changes. Proceed as normal
Changes to Control Tower, purely informational. Procced as normal.
Changes with possible impact to workflow. Proceed with caution.
Changes with definitive impact to workflow. Do not use until fixed.

## Multimedia Appendixes

Source code for a demo of the Control Tower Model Monitoring R Shiny application.
URL: http://asset.jmir.pub/assets/5c90e1bc5736d2448bc1bd14a74f28dd.zip