

A Shiny New Audit Trail Review (ATR) Dashboard

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Why ATR Matters in Modern Clinical Trials



Audit trails provide transparency on **how trial data are created and modified**



They underpin **data integrity, traceability, and credibility of results**

Why ATR Matters in Modern Clinical Trials

Essential

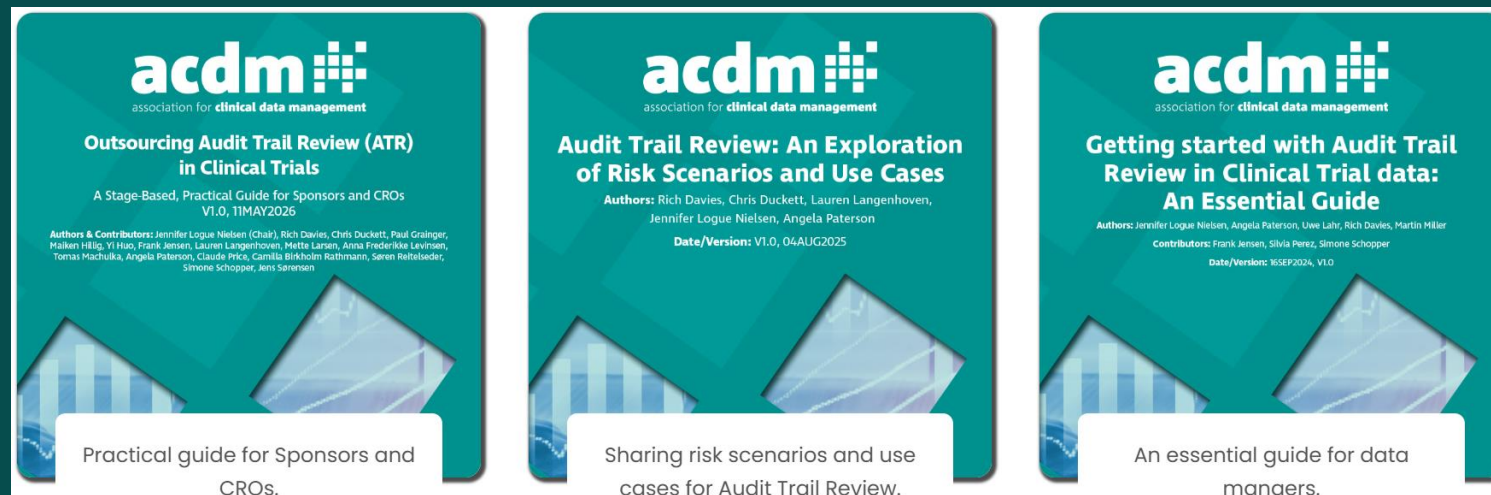
- Demonstrating ICH E6(R3) GCP compliance
- Understanding data changes over time
- Detecting errors, unusual behaviour, process issues

Increasing importance

- Fully electronic data capture
- Decentralised and hybrid trials
- Remote oversight and central monitoring

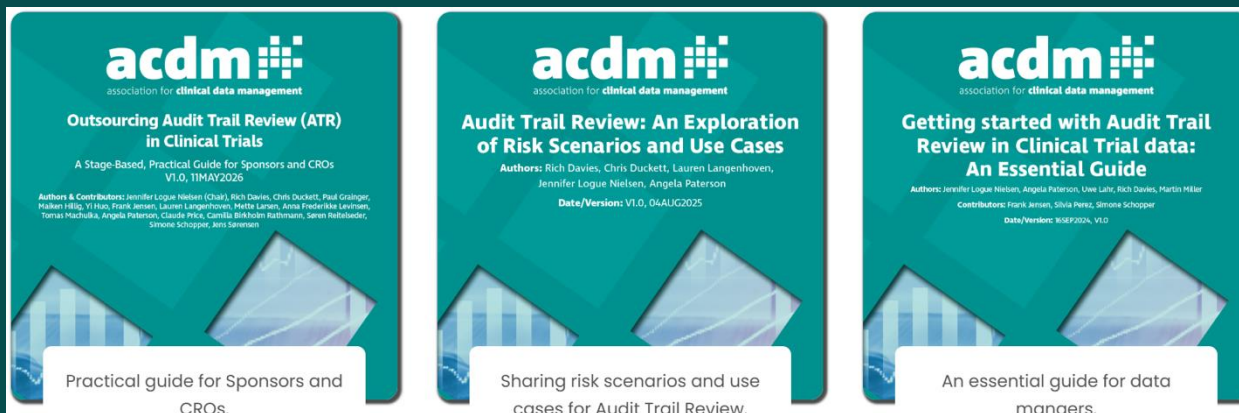
A Risk-Based Approach to ATR

- The ACDM has developed several guides to start with ATR.
 - ATR should take place using a risk-based quality management approach.



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We developed an in-house ATR dashboard that allowed for adaptation based on study needs

Development of the Audit Trail Dashboard

- **R Shiny**: open-source R for dashboard development



```
#' @export
ui <- function(id) {
  ns <- NS(id)
  dashboardPage(
    # load page layout
    dashboardHeader(
      color = "purple",
      title = "Audit Trail Review Dashboard",
      logo_path = "static/logo_RGB_text.png",
      inverted = TRUE
    ),
    dashboardSidebar(
      sidebarMenu(
        menuItem("Home", tabName = "Home", icon = icon("home")),
        menuItem("ATR overview", tabName = "atr_overview", icon = icon("font-awesome")),
        menuItem("ATR trends", tabName = "atr_trends", icon = icon("chart-line"))
      )
    ), # end dashboardSidebar
    dashboardBody(
      tabItems(
        tabItem(
          tabName = "atr_overview",
          atr_overview$ui(ns("atr_overview"))
        ),
        tabItem(
          tabName = "atr_trends",
          atr_trends$ui(ns("atr_trends"))
        )
      ) # end tabItems
    ) # end dashboardBody
  ) # end dashboardPage
}

#' @export
server <- function(id) {
  moduleServer(id, function(input, output, session) {
    atr_overview$server("atr_overview")
    atr_trends$server("atr_trends")

    session$onSessionEnded(function() {
      stopApp()
    })
  })
}
```

Development of the Audit Trail Dashboard

- **R Shiny**: open-source R for dashboard development
- **Rhino**: framework



```
▼ app
  > js
  > logic
  > static
  > styles
  > view
  🔍 main.R
  > bin
  > data
  > renv
  > tests
  🔍 app.R
  ! config.yml
  🔍 dependencies.R
  ⚡ DEVELOP.md
  ≡ infoafter.txt
  ≡ infobefore.txt
  ⓘ README.md
  ≡ renv.lock
  ! rhino.yml
```

```
box::use(
  app / view / atr_overview,
  app / view / atr_trends,
  app / logic / load_data,
)

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Development of the Audit Trail Dashboard

- **R Shiny**: open-source R for dashboard development
- **Rhino**: framework
- **tidyverse** and **data.table**: data wrangling and transformation



```
study_data$atr <- study_data$atr[, user_email := stringr::str_extract(`Audit User`, "[[:alnum:]]+@[[:alnum:]]+\\.+")]
study_data$atr <- study_data$atr[grepl("^Query", `Audit Description`), query_type := stringr::str_split_i(`Audit Description`, ":", 1)]
study_data$atr <- study_data$atr[, siteid := substr(Subject, 1, 5)]

study_data$form_data <- extract_form_metadata(study_data$atr)
study_data$item_data <- extract_item_metadata(study_data$atr)

study_data$atr_total_items <- study_data$atr[Object == "Item", .(recordid = unique(`Record ID`)), by = .(siteid, `Event Group`, Event,
Form, `Item Group`, Item)][, .(total_items = .N), by = siteid]
study_data$atr_total_forms <- study_data$atr[Object == "Form", .(recordid = unique(`Record ID`)), by = .(siteid, `Event Group`, Event,
Form, `Item Group`, Item)][, .(total_forms = .N), by = siteid]

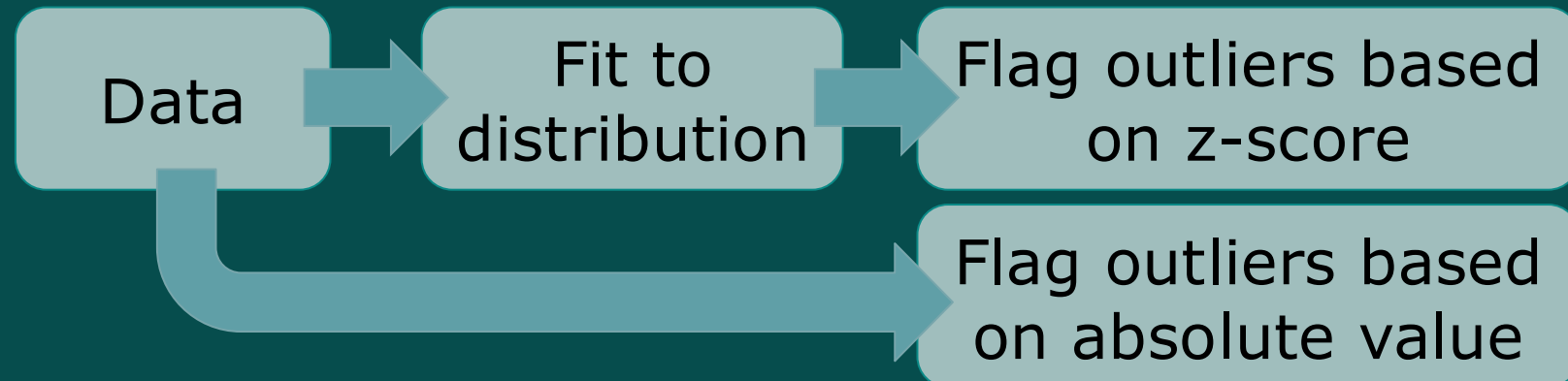
atr$form_changes <- List(
  ID = "StatusChangeForm",
  data = study_data$form_data[!is.na(new_submit_nr) & new_submit_nr > 1][ # because 0, 1 are creation and first submission
    , .(changes = .N),
    by = .(`Record ID`, siteid, Event, `Event Group`, Form)
  ][
    , .N,
    by = .(siteid, changes, Event, `Event Group`, Form)
  ],
  rel_threshold = c(2, 3),
  abs_threshold = c(2, 4)
)
```

Development of the Audit Trail Dashboard

- **R Shiny**: open-source R for dashboard development
- **Rhino**: framework
- **tidyverse** and **data.table**: data wrangling and transformation
- **gsm.core**: statistical testing

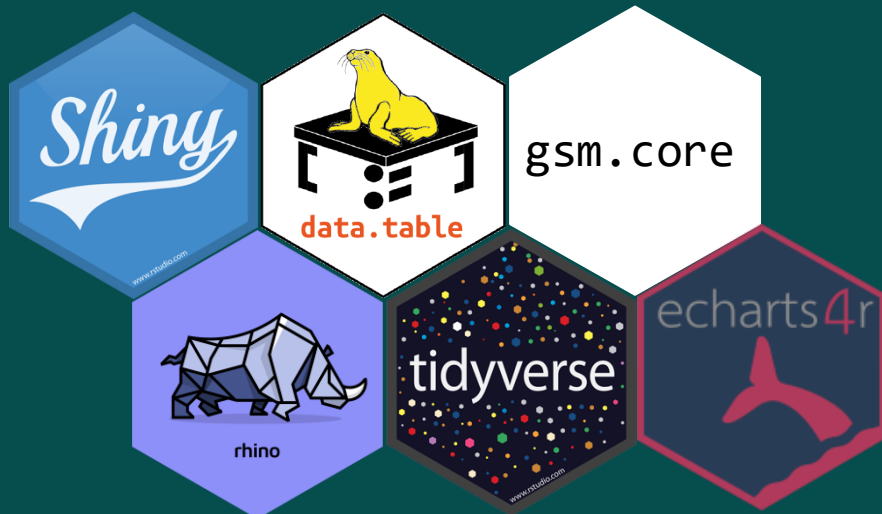
```
<data> |>  
  Transform_Rate(strNumeratorCol = "N",  
                strDenominatorCol = "total_forms") |>  
  Analyze_NormalApprox(strType = "rate") |>  
  Flag(vThreshold = atr$form_changes$rel_threshold,  
        vFlag = c(0, 1, 2),  
        vFlagOrder = c(2, 1, 0))
```

```
<data> |>  
  Flag(  
    strColumn = "mean_changes",  
    vThreshold = atr$form_changes$abs_threshold,  
    vFlag = c(0, 1, 2),  
    vFlagOrder = c(2, 1, 0)  
  ) |>  
  _[, .(  
    GroupID = siteid,  
    GroupLevel = "SITENUM",  
    Metric = mean_changes,  
    Flag  
  )  
]
```



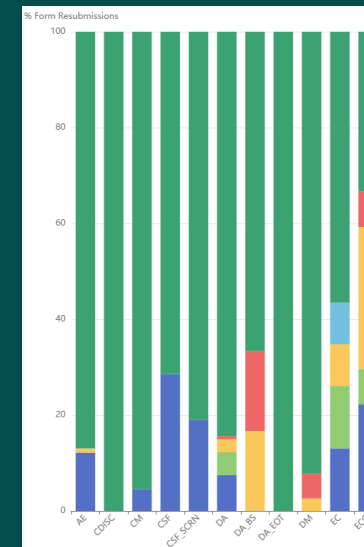
Development of the Audit Trail Dashboard

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- **Rhino**: framework
- **tidyverse** and **data.table**: data wrangling and transformation
- **gsm.core**: statistical testing
- **echarts4r**: data visualisation



```
<data> |>
  group_by(changes) |>
  e_charts_(level)
}

plot <- plot |>
  e_bar(perc, stack = "grp", focus = "series") |>
  e_x_axis(axisLabel = list(interval = 0, rotate = 45)) |>
  e_axis_labels(x = level, y = "% Form Resubmissions") |>
  e_y_axis(max = 100)
```



Issues and Lessons During Development

Audit trail
contained data
on several levels
in long format

Data was filtered on the relevant
level (form/item) before
performing the analyses

Audit Timestamp	Audit User	Study	Site	Subject	Event Group	Event	Form	Item Group	Item	Assessment	Object	Record ID	Record Name	Audit Description
10-Jun-2026 15:00:00 UTC	Maylin	<Study name>	Health Research Center	1							Subject	1		Subject : 1 created
10-Jun-2026 15:01:00 UTC	Maylin	<Study name>	Health Research Center	1							Casebook	PAT-0001		Casebook : PAT-0001 created
10-Jun-2026 15:02:00 UTC	Maylin	<Study name>	Health Research Center	1	SCR						Event Group	VV-000001	SCR	Event Group : VV-000001 created

Issues and Lessons During Development

Action
descriptions were
in structured free
text

Relevant information was
extracted and added as
structured data

Audit Description

Casebook : SCR-0001 created

Event : VV-000001 created

"Event Date SDV Mode" set to "Required"

"SDV Mode" set to "Required"

"Form Status" changed from "In Progress" to "Submitted"

"Subject Status" changed from "In Screening" to "Screen Failure"

Derivation submit value set as Intentionally Left Blank with reason "Assessment not performed".

"Change Reason" set to "Query response"

"Assessment not performed" was removed from the "Intentionally Left Blank Reason" field.

"Change Reason" changed from "User set Intentionally Left Blank" to "Query response"

"Intentionally Left Blank" changed from "false" to "true"

"Did Not Occur" set to "true"

"Casebook Definition" changed from "2" to "3"

Issues and Lessons During Development

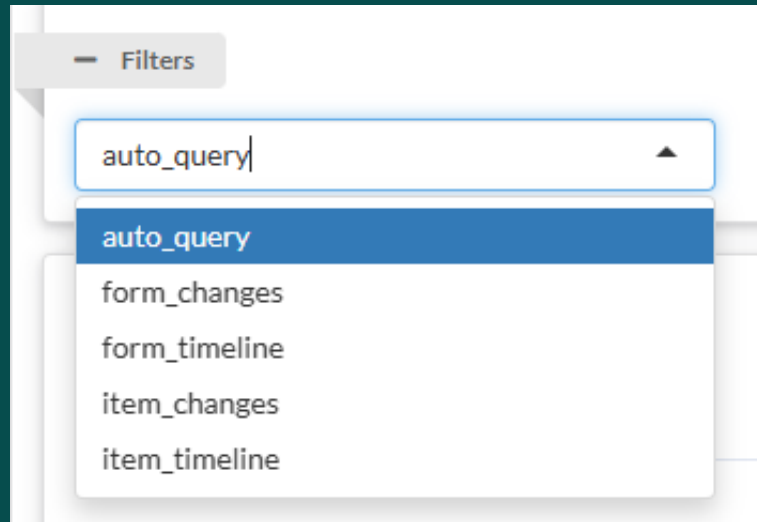
Statistical analyses must have a minimum number of samples to have enough power

Descriptive analyses were added to monitor the data even when no statistical tests could be performed

Current Audit Trail Dashboard

ATR Overview

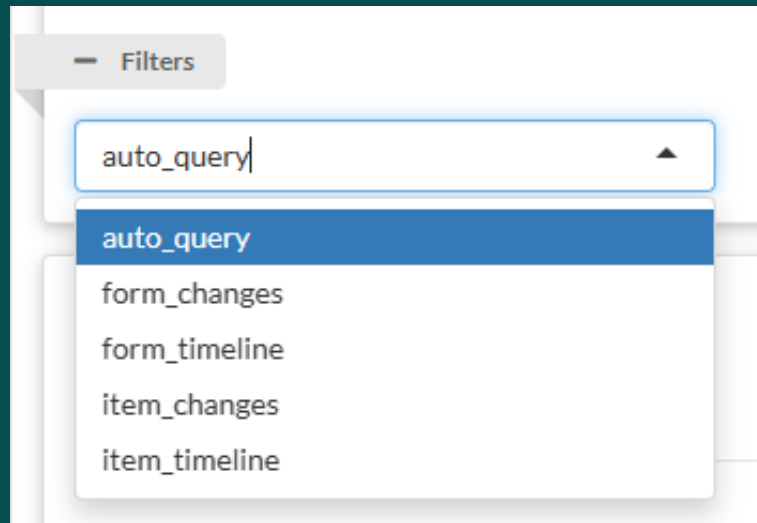
Visualisations of audit trail data can be selected on query-, form-, and item-level.



Current Audit Trail Dashboard

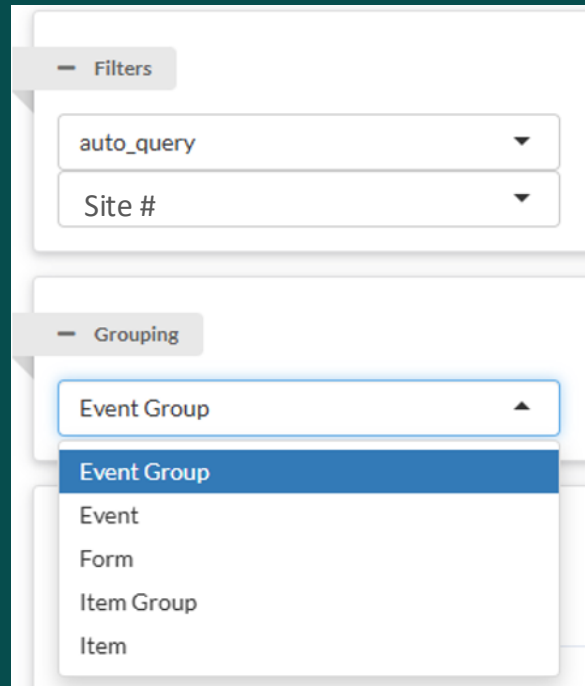
ATR Overview

Visualisations of audit trail data can be selected on query-, form-, and item-level.



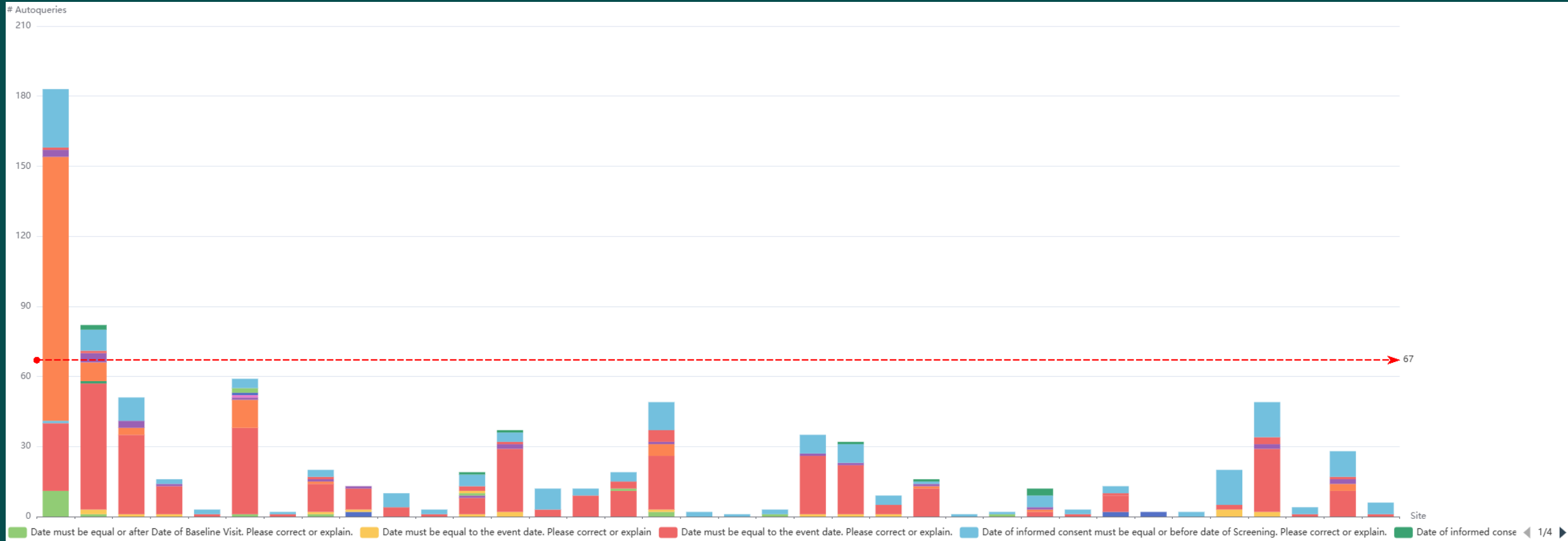
ATR Trends

The data can be grouped by additional categorizations to view trends per site.

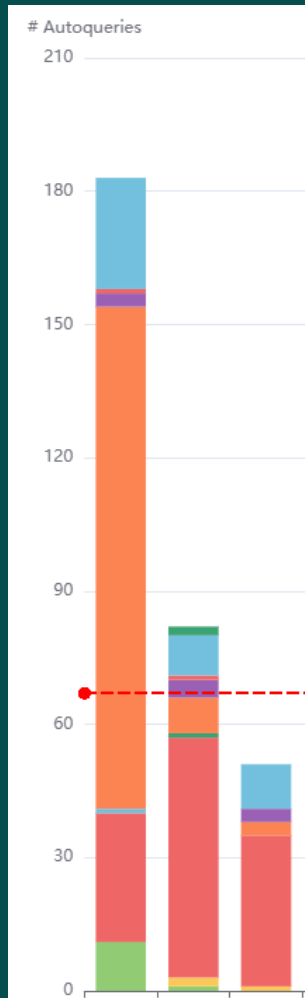


Filter and grouping options depend on study set-up and content of ATR exports.

Example ATR Overview – Auto-Query



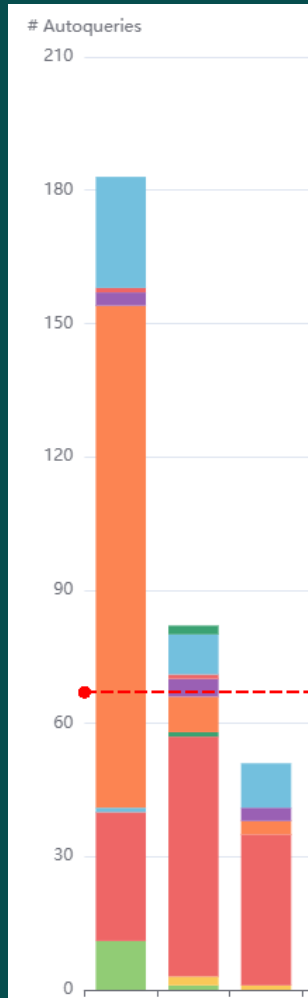
Example ATR Overview – Auto-Query



Number of auto-queries per site and query-category

- Treatment Dispensation Date must be equal to Date of Visit
- Date must be equal to the Event Date
- Date of informed consent must be equal to or before Date of Screening

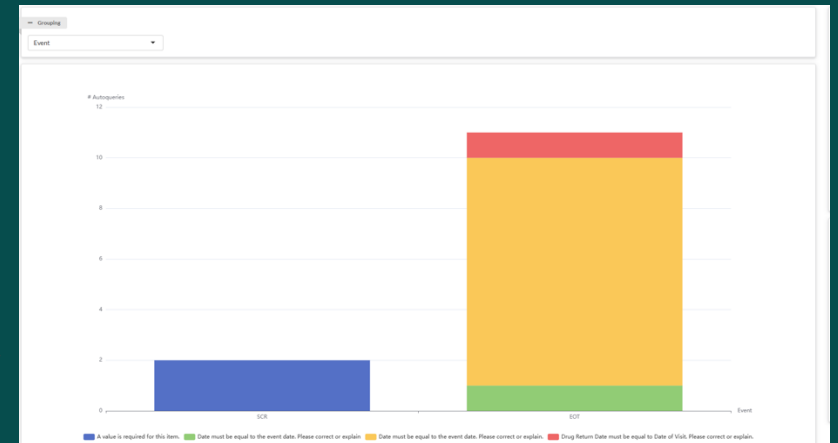
Example ATR Overview – Auto-Query



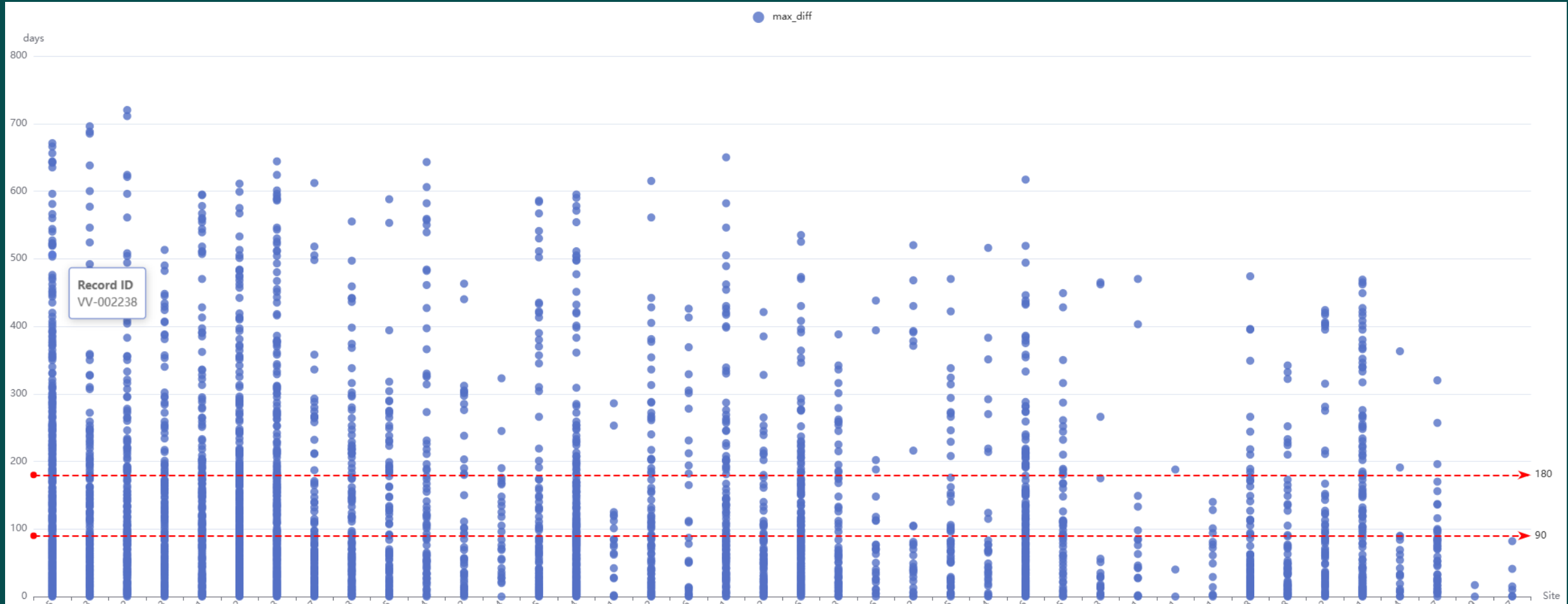
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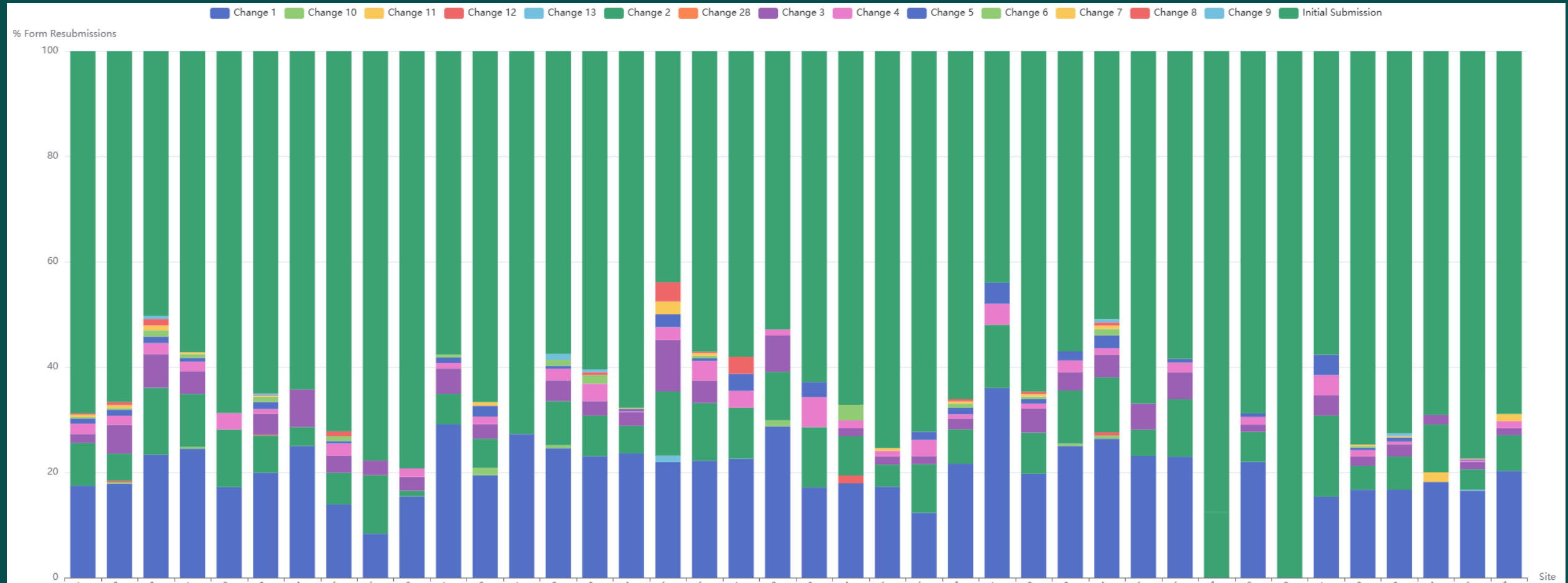
Details per site and selected grouping variables can be viewed in the ATR Trends



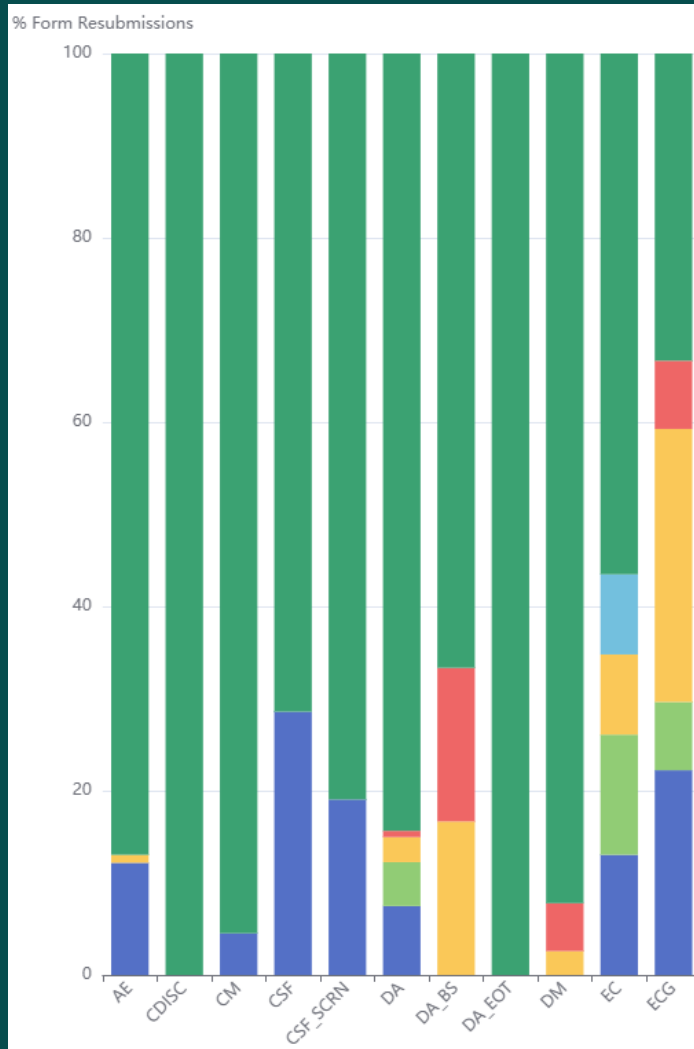
Example ATR Overview – Form Timeline



Example ATR Overview – Form Changes



Example ATR Trends – Item Changes per Form



Filters

item_changes

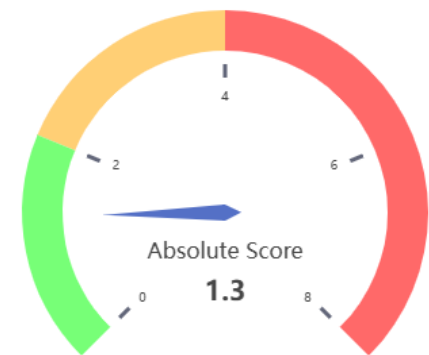
Site #

Grouping

Form

Change 1 Change 2 Change 3

Change 4 Change 5 Initial Submission



Interpreting Results: Risks and Challenges

Interpretation requires context

- Context is required to draw conclusions on data quality, process inefficiencies, or (un)expected query activity

Signal detection is complex

- Identifying relevant signals vs noise
- Overlooking critical signals vs over-reviewing low-risk data
- Risk of false positives/negatives

Bias and visual pitfalls

- Relative comparison bias (e.g. SD-based thresholds)
- Misleading visualisations

Interpreting Results: Good Practices



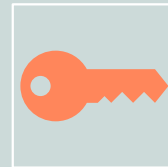
Targeted and risk-based review



Context-driven interpretation



Regular review of signals vs noise



Key principle: Prove control, not volume

Future Developments in ATR

Optimise focus of risk indicators on study-specific risks

- More context-aware indicators to flag signals relevant for a specific study

Performance optimisation

- Optimise processing of large AT exports for faster dashboard refresh and integrate multiple AT sources

Visual design improvements

- Refine visualisation (such as colour usage, threshold marking, summaries) to support correct interpretation

Develop comprehensive user guidance

- Develop integrated interpretation support such as examples or recommended actions



"Don't follow every trail, follow the right one."

Thank you!

Contact details

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