Metrics Manual

Metrics for Health and Medical Research, including Clinical Trials

NSW minimum dataset for health and medical research, including clinical trials

Office for Health and Medical Research – Version Date: March 2022

Background

The Office for Health and Medical Research started collecting ethics and governance metrics for inclusion in the Chief Executives Service Agreements in 2016. The program has dual intents:

(1) to provide quantitative empirical evidence to present an accurate description of ethics and governance approval and authorisation timeframes to counterbalance anecdotal misinformation; and

(2) to provide objective, comparative information to enable public health organisations to use data analysis to drive process improvement; to demonstrate benchmarking opportunities with other institutions; and ultimately, to contribute to robust statewide performance, establishing NSW as a rapid and efficient study start up jurisdiction for high quality and ethical research.

The data collection for the minimum dataset for health and medical research in NSW PHOs started in 2016 to provide quantitative evidence to portray an accurate picture of the research projects approval and enrolment timelines. The Office for Health and Medical Research (OHMR) has since implemented reform initiatives which aim at contributing to a significant and sustained improvement in NSW's ability to initiate and deliver health and medical research, including clinical trials. Using the dataset collected, NSW PHOs are now at the stage to engage deeper into the conversation to recognise improvements made and further opportunities for review service enhancement.

This document is an updated version of the March 2016 document "Metrics for Health and Medical Research, including Clinical Trials", which detailed the strategic and site level performance and compliance metrics collected by the Office for Health and Medical Research (OHMR) on behalf of the Ministry of Health from NSW Public Health Organisations (PHOs) since July 2016. The metrics collected are in line with the Key Performance Indicators (KPI) included in Service Agreements between PHO Chief Executives (CEs) and the Secretary of Health.

This document outlines Key Performance Indicator (KPI) thresholds and illustrations of measurement calculations. Additionally, it outlines the REGIS database fields, data quality requirements, and other system functionality that OHMR will use to report metrics-related data within the Ministry of Health and to CEs of NSW Public Health Organisations and NSW Ambulance.

Please contact the Research Ethics and Governance Unit at moh-researchethics@health.nsw.gov.au with any questions about metrics data recording or reporting.

Setting Objectives

NSW Health wishes to promote health and medical research, so that the population it serves can benefit from improved access to the most advanced clinical trials, its workforce can develop expertise in research methods, the PHOs can reflect on and enhance the quality of their clinical services. The following are the objectives so that stakeholders understand OHMR's expectations and can work towards the same goals.

NSW Level Objectives

- To optimise the number of clinical trials conducted in NSW
- To reduce the time taken to obtain research approvals (HREC & SSA)
- To increase the proportion of trials in NSW that enrol the agreed number of participants within the agreed timeframe

Operational objectives relating to research projects start-up and delivery at site

- HREC - To engage all stakeholders in the HREC review process to continuously improve the quality of HREC submissions and to reduce the time taken for ethics approval
- Governance - To engage all stakeholders in the Site Specific Assessment (SSA) process to continuously improve the quality of site submissions and to reduce the time taken for site authorisation
- Governance - To improve trial delivery at the site by increasing the number of trials that enrol the agreed number of participants within the agreed timeframe
- To improve the quality and compliance of clinical trials conducted in NSW

Metrics

A metric is defined as *any type of measurement used to gauge some quantifiable component of an entity's performance*. Metrics were collected initially using the information system AU RED from 2016, and then REGIS since 2018.

Two categories of metrics are used:

1. **NSW LEVEL STRATEGIC METRICS**: State Level Metrics that measure the synergy through the engagement of all stakeholders within NSW Health system.

2. **SITE LEVEL METRICS**: Metrics used to drive internal process improvement and to identify progress in customer service to the sector. Individual institutions may wish to use their site-level metrics to advertise their competitive position or identify support they need from within their institution. These metrics have been collected prospectively from July 2016.

OHMR periodically report on a selection of site level performance metrics to monitor the changing research ethics and governance landscape. These selected monitoring measures are incorporated into the service agreement between PHO CEs and the Secretary of Health:

KPIs and Monitoring Metrics:

To facilitate the implementation of the metrics data collection and performance improvement, a selection of the Strategic and Performance Metrics are to be included in the service agreements between PHO CEs and the Ministry of Health as KPIs and Monitoring Metrics for the performance of the research offices. These metrics have been collected prospectively from July 2016.

A **Metrics Activity Report** was originally generated bi-annually from July 2016 to report on the KPIs and monitoring measures. The frequency was switched to quarterly from 2019.

Changes to the KPI calculations and performance benchmarks came into effect at the beginning of July 2021. The updated metrics were also included in the service agreements between PHO CEs and the Ministry of Health for the financial year 2021/22. This document incorporated these updates.

Interpretation of the Metrics – how the Metrics Activity Report is expected to be used

Since July 2021, the KPIs reported by OHMR moved from research office time to the end-to-end total time time the users /applicants experience, from submitting a complete application to being notified of the

decision. This is to focus less on the research office processing time and put the emphasis on the strategic goal of improving overall timeline in the research projects approval and enrolment process. The metrics are quantitative evidence that informs on challenges and opportunities for process enhancement which can guide the stakeholders' collaboration to create a more attractive environment for health and medical research.

The total time and breakdown time for all parties involved in the review process informs on the potential process improvement opportunities, and whether the solution implemented is effective.

If a PHO identifies prolonged researcher response time, the research office can work with their researchers to find out the extra support that they may need; if head of department breakdown time is taking up 90% of most the approval timelines, more resources may be put to engage this group; if the Chief Executives or HREC Chairs are less available to decide on certain issues, the alternative of a delegated decision maker may be discussed.

For an example: one Sydney PHO's percenter of site applications approved within 60 days (Metric 4) has dropped significantly from last reporting period, as shown in the Metrics Activity Report. The CE notices the delay in approvals and enquired to find that during the last quarter, one of the experienced research governance officers has left the research office, and the recruit has not onboarded yet. This PHO's Metric 4 result kept improving in the next two reporting periods to their usual level, which indicates the recruit successfully onboarded and is properly trained to carry out the full responsibility entailed by the role.

The body of this document is divided into five parts:

- **Section 1: NSW and site-level metrics**
    - NSW Strategic Metrics 1 and 2 are not listed in Service Agreements as they relate to state-wide objectives. These two metrics are derived from data points collected from Performance/Compliance Metrics 3-7.
        - Site Level Metrics 3-7 are reported by OHMR via REGIS. These metrics are used to calculate the KPIs, and Monitoring Measures described in Section 3 &4.

- **Section 2: Non-reportable quality and transparency metrics for internally-sponsored clinical trials, for optional use within an institution**
    - Non-reportable metrics which are optional but valuable and which may be collected and utilised by institutions to further research quality and transparency objectives in support of state-wide initiatives.

- **Section 3: KPIs in CE's Service Level Agreement**
    - Metric 3 and 4 are the KPIs included in the CE's Service Level Agreements.
        - KPI21-03 and KPI21-04

- **Section 4: Monitoring Measures**
    - Monitoring Measures that will be included in the CE's Service Agreements.

- **Section 5: Metrics Activity Report and Data Quality**
    - Metrics Activity Report
    - Dataset and Reporting Quality Control

- **Appendix 1: Definitions for key terms.**
- **Appendix 2: Diagram for REGIS workflow diagram and KPIs Calculation (Metric 3 and 4)**

SECTION 1: STATE-LEVEL STRATEGIC METRICS AND SITE-LEVEL METRICS

OVERARCHING

	Metric Category & Description	Objective	Measure	Primary Data Fields Required*	Comments
All Commercial Trials	**1. Strategic:** Number of New Commercial Trials in NSW in the reporting year	1) To assess whether NSW is attracting more commercial trials 2) To increase the access to commercial trials for the NSW patient population	State Level: Total number of new commercial clinical trials in a reporting year	• Application unique identifiers** • Ethics Review Pathway*** • Sponsor Type: Commercial Entity • Study type: Clinical trial	The first reporting year will provide the baseline data for comparison with future reporting years. No associated Monitoring Measures.

* This document illustrates the primary data fields that are required to enable the metrics to be collected. Secondary level data fields in REGIS will also be utilised.
** A unique study and site identifier would be required for all metrics.
*** Ethics Review Pathway: Low & Negligible Risk (LNR) or Greater than Low Risk studies. LNR/non LNR status would be required for all metrics.

STUDY SET-UP

	Metric Category & Description	Objective	Measure	Primary Data Fields Required*	Comments
All Commercial Trials	**2. Strategic:** NSW HREC Submission Closing Date to First NSW Participant Enrolled	1) To reduce total time taken to obtain trial approvals/authorisations in NSW 2) To reduce the time to first participant enrolled 3) To identify bottlenecks outside the control of the HREC/Governance office	State Level: Median number of calendar days from NSW HREC closing date to first NSW participant enrolled at any participating site	• NSW full HREC meeting submission closing date • First participant enrolled (NSW site) • Time stamps of study status change • Sponsor Type: Commercial Entity • Study Type: Clinical trial • Study Status	The first reporting year will provide the baseline data for comparison with future reporting years. No associated Monitoring Measures.

STUDY SET-UP CONTINUED

	Metric Category & Description	Objective	Measure	Primary Data Fields Required	Comments
All Research (except LNR)	**3. Site-level:** NSW HREC Submission Closing Date to NSW HREC Approval*	1) To assesses the efficiency of the HREC's processes and 2) To drive process improvement	Site Level: Number of calendar days to HREC approval	• HREC full meeting submission closing date • Time stamp of status change • Date of HREC approval • Study status (e.g. withdrawn) • Review Pathway • Study Type • Sponsor Type	**Possible valid reasons for delay:** Applications with prolonged in-activity on the researcher's side for a period specified in the terms of reference of the reviewing HREC, which is eligible to be withdrawn but not withdrawn by the researcher, Research office, or REGIS system yet. *** Associated monitoring measure: 1
	4. Site-Level: Date SSA Application with evidence of Ethics Approval** Received by the RGO to Site Authorisation	1) To assess the efficiency of the site authorisation process and 2) To drive process improvement	Site Level: Number of calendar days to site authorisation	• Date SSA application received • Date evidence of ethics approval received • Time stamp of status change • Date of site authorisation • Study Status (e.g., withdrawn) • Ethics Review Pathway • Study Type • Sponsor Type	**Possible valid reasons for delay:** Applications with prolonged inactivity on the researcher's side not withdrawn by the Researcher, Research office, or REGIS system yet. *** Associated monitoring measure: 2

*Breakdown of the Metric 3 and Metric 4 total time will be included in the metrics activity report. For example, Researcher Time measures the length of time it takes for the investigator/sponsor to fully address the queries raised by the approval body. There may be multiple requests for further information during the approval process, if the investigator fails to address the HREC's or institution's feedback or if new information provided by the investigator generates additional queries from either approval body, the HREC or Research Office.

**Where the ethics approval of the SSA is granted by one of the NSW Health HREC within the REGIS system, the evidence of Ethics Approval for the Metric 4 performance is the ethics approval notification email. Where ethics approval is granted external to REGIS under the National Mutual Acceptance scheme, the evidence of Ethics Approval is recognised when the Ethics approval notification email is uploaded to the SSA application.

***Withdrawn applications are not reportable for the metrics report. If an application is approved, the study continues to be active for post-approval progresses. If an application is withdrawn by the applicant or the research office, the applicant can only re-submit the study as a new project and go through the complete review

process from the start. If the Research Office initiates the withdrawal, the research officer must comply with the principles of procedure fairness, using all efforts to communicate any adverse information to the researchers(e.g., the withdrawal and the need to resubmit).

STUDY DELIVERY

	Metric Category & Description	Objective	Measure	Primary Data Fields Required	Comment
All Commercial Trials	**5. Site-level** Sites enrolling their first participant within 40 calendar days of Site Specific Authorisation	To reduce the time taken to enrol first participant into commercial trials conducted in NSW	Site Level: Proportion of commercial trials with at least one participant enrolled by Day 40 post Site Specific Authorisation State Level: Proportion of sites with at least one participant enrolled by Day 40 post Site Specific Authorisation. (Derived by OHMR)	• Study type: Clinical trial • Sponsor Type: Commercial Entity • Date of SSA • Date first participant enrolled • Study Status (e.g. trial terminated) • Valid reason for not enrolling within 40 days, if applicable	**Possible valid reasons for not enrolling within 40 days:** Examples* include: • Study closed to enrolment or terminated by the sponsor before the 40 day deadline • Significant sponsor-related delay in Site Activation • Other (specify)
	6. Site-level: Sites reaching or exceeding their agreed enrolment target as per contract	To increase the number of commercial trials that achieve or surpass their enrolment target	Site Level: Proportion of trials reaching or surpassing their enrolment target at study closure State Level: Proportion of trials reaching or surpassing their enrolment target at study closure (Derived by OHMR)	• Study Type: Clinical trial • Sponsor Type: Commercial Entity • Minimum enrolment target at site per CTRA** • Actual enrolment at site • Study Status (e.g. trial terminated date) • Valid reason for not reaching enrolment target, if applicable	**Possible valid reasons for not reaching target:** Examples* include: • Study closed to enrolment or terminated by the sponsor before agreed completion date • Rare or very rare disease making enrolment difficult to predict up front. • Very small patient population due to age group to be treated making enrolment difficult to predict up front. • Other (specify)

*To be documented at time of report and to be assessed/validated centrally
** The contract or agreement may quote a minimum and maximum target to enable a site to over-recruit without having to alter the agreement.

STUDY REPORTING

	Metric Category & Description	Objective	Measure	Primary Data Fields Required	Comment
All Research*	**7. Site-level:** Progress reports (including final progress reports) submitted by NSW PI/CPI to his/her HREC within the required timeframe	To improve compliance with study annual/interim/final progress reporting to the NSW institution	Site level: Proportion of studies that complied with annual/interim/final progress reporting to their HREC	• Application ID • Application Milestone	**Possible valid reasons for not reaching target:** Nil

*Breakdown by GTR/ LNR

SECTION 2: NON-REPORTABLE QUALITY AND TRANSPARENCY METRICS FOR OPTIONAL USE WITHIN AN INSTITUTION

STUDY QUALITY AND TRANSPARANCY				
	Metric Category & Description	**Objective**	**Measure**	**Recommended Data Fields**
All Internally Sponsored Clinical Trials	**8. Transparency:** Internally sponsored clinical trials in NSW that are registered on a publicly accessible database before the first participant is enrolled	To improve the transparency of internally sponsored NSW clinical trials through compliance with international trial registration requirements	Study Level: Proportion of internally sponsored NSW trials registered on a publically accessible database before the first participant is enrolled	Available in REGIS: • Study type: Clinical trial • Sponsor Type: Institution • Milestone: Date first participant enrolled Other • Date study registered on the chosen registry • Valid reason for delayed registration
	9. Quality/Transparency: Protocols for internally sponsored clinical trials in NSW that comply with the 33-item SPIRIT checklist	To improve the quality of internally sponsored NSW clinical trial protocols through compliance with international standards	Site Level: Proportion of internally sponsored NSW trials with protocols that include all elements described in the SPIRIT checklist	Available in REGIS: • Study type: Clinical trial • Sponsor Type: Institution Other • Protocol content assessed* as satisfactorily meeting the SPIRIT checklist (Y/N)
	10. Transparency: Reports of trial summary results (Summary Reports) for internally sponsored clinical trials in NSW posted publically** within 12 months of Study Completion	To increase trial accountability and results uptake through improved compliance with international results reporting timelines	Study Level: Proportion of internally sponsored NSW trials that publish a Summary Report within 12 months of Study Completion	Available in REGIS: • Study type: Clinical trial • Sponsor Type: Institution • Milestone: Date final report was submitted Other • Summary Report posted publically within the 12 month timeframe (Y/N) • Valid reason for not meeting reporting requirements
	11. Quality/Transparency: Full reports of trial results (Final Study Reports) for internally sponsored clinical trials in NSW that comply with the 25-item CONSORT checklist or where applicable CONSORT Extensions	To facilitate the complete and transparent reporting of internally sponsored NSW Clinical Trials in compliance with international trial reporting recommendations	Site Level: Proportion of internally sponsored NSW trials that produce Study Reports that comply with the CONSORT Checklist (or where applicable, CONSORT Extension Checklists)	Available in REGIS: • Study type: Clinical trial • Sponsor Type: Institution Other • Study Report received in the reporting year (Y/N) • Study Report assessed*** as satisfactorily meeting the reporting requirements outlined the CONSORT checklist or CONSORT Extensions Checklist (Y/N)

* It is suggested that to assess compliance with this metric, institutions develop/adopt a SPIRIT-compliant protocol template.
** The summary of results should be made publicly available at the same place where the trial was registered. For trials registered on ANZCTR, alternative arrangements (such as publication on a Summary Report Section of the institution's website) will be needed as there is currently no results reporting functionality.
***It is suggested that to assess compliance with this metric, researchers provide an annotated copy of the relevant Consort Checklist, which cross references to content within the Study Report.

SECTION 3: KPIs in the CE agreements

Measures	Frequency of Reporting	Target		
		Not Performing	Underperforming	Performing
Metric 3 (KPI21-03) -- Ethics applications involving Greater than low risk to participants approved by the reviewing HREC within 90 calendar days (%)	Quarterly	<55%	≥ 55% and < 75%	Target of 75% met or better
Metric 4 (KPI21-04) – Site specific applications involving more than low risk to participants authorised within 60 calendar days (%)	Quarterly	<55%	≥ 55% and < 75%	Target of 75% met or better

An illustration of measurement calculation:

Metric 3 (KPI21-03): ethics applications involving greater than low risk to participants approved by the reviewing HREC within 90 calendar days (%)				
Date of submission closing date for the first HREC full meeting at which HREC application will be considered	to	Date of approval notification email sent to investigator	equals	Total no. of calendar days from HREC meeting submission closing date to approval
01/07/15	to	01/09/15	=	62 days
No. of ethics applications approved within 90 days	Divided by	Total No. of approved ethics applications	equals	% approved within 90 days
6	÷	9	=	66.7%
Metric 4 (KPI21-04): site specific applications involving greater than low risk to participants authorised by the reviewing RGO within 60 days (%)				
Date of receipt of a site-specific assessment application with evidence of Ethics Approval** at a site's research office	to	Date of site authorisation email sent to investigator	equals	Total no. of calendar days from SSA submission (with evidence of Ethics Approval) to authorisation
01/07/15	to	01/09/15	=	62 days
No. of site applications authorised within 60 days	Divided by	Total No. of authorised site applications	equals	% approved within 60 days
13	÷	15	=	86.7%

** Where the ethics approval of the SSA is granted by one of the NSW Health HREC within the REGIS system, the evidence of Ethics Approval for the Metric 4 performance is the ethics approval notification email. Where ethics approval is granted under the National Mutual Acceptance scheme, the evidence of Ethics Approval is recognised when the Ethics approval notification email is uploaded to the SSA application.

Section 4 MONITORING MEASURE INDICATORS – INCLUDED IN CE SERVICE AGREEMENTS

Metric 5 First participant enrolled to a commercial clinical trial by the site within 40 calendar days of site authorisation (%)	Bi-annual	80	<75%	≥ 75% and < 90%	Target of 90% met or better
Metric 6 Actual participants enrolled to a commercial clinical trial project as a proportion of those initially agreed to be enrolled per the Clinical Trial Research Agreement (CTRA) minimum target (%)	Bi-annual	100	<50%	≥ 50% and < 75%	Target of 75% met or better
Metric 7 Progress reports on all authorised research projects received at least annually and at study close (%)	Annual	90	<75%	≥ 75% and < 90%	Target of 90% met or better

Metric 5: First participant enrolled to a commercial clinical trial by the site within 40 days of site authorisation (%)							
Date of Site Authorisation	to	Date 1st participant is enrolled	equals	Number of calendar days taken for 1st participant enrolment		Valid reason for delay (Y/N/Not applicable-NA)	Target met
01/07/15	to	07/8/15	=	37 days		N/A	
Alternative example:							
Date of Site Authorisation	to	Date 1st participant is enrolled	equals	Number of calendar days taken for 1st participant enrolment		Valid reason for delay Y/N/Not applicable (NA)	
01/07/15	to	07/9/15	=	68 days		Y 1 month delay in site activation which occurred on 6/8/15	Trial removed from the Indicator assessment because of valid reason for not meeting the target

Metric 6: Actual participants enrolled to a commercial clinical trial project as a proportion of those initially agreed to be enrolled per the CTRA minimum target (%)					
Planned participants per CTRA minimum target	Actual Participants enrolled at trial close	Actual/Planned X 100	Valid reason for not meeting enrolment target (Y/N/NA)	equals	Actual/Planned X 100
10	8	80%	NA	=	80%
Alternative example:					
Planned participants per CTRA minimum target	Actual Participants enrolled at trial close	Actual/Planned X 100	Valid reason for not meeting enrolment target (Y/N/NA)		
10	4	40%	Y Worldwide enrolment target achieved six months before anticipated completion date so site only open for 4 months	=	Trial removed from the Indicator assessment because of valid reason for not meeting target

Metric 7: Progress reports on all authorised research projects received at least annually and at study completion (%)					
No of progress/final reports due in the reporting year	No of progress/final reports received	Actual/Planned X 100		=	Target Met
74	68	92		=	92%

Section 5: Metrics Activity Report and Data Quality

Metrics Activity Report

KPIs	Content	Details
KPI21-03: Ethics Review Timelines of Human Research in NSW PHOs	Summary:	A summary of the all-NSW ethics review performance: total number of applications, clinical trials, and average total time.
	Table 1:	All greater than low risk ethics approval within the reporting period broken down by NSW PHOs: - Number of Applications. - Number and percentage of applications approved within 90 days. - Average total time and average breakdown by the processing time of research office and researcher response time. - Count of requests for further information sent to researchers.
	Table 2:	All clinical trials ethics approval within the reporting period broken down by NSW PHOs: - Number of Applications. - Number and percentage of applications approved within 90 days. - Average total time and average breakdown by the processing time of research office and researcher response time. - Count of requests for further information sent to researchers.
	Table 3:	Performances in clinical trial ethics approvals broken down by sponsor type and NSW PHOs: - Number of Applications. - Average total time. - Average Research office processing days.
	Table 4:	All NSW performance in clinical trial ethics approvals (greater than low risk) broken down by sponsor type and quarter of the year: - Number of Applications. - Average total time. - Average Research office processing days.
	Table 5:	Performance of NSW PHOs against the old and new benchmarks for ethics approvals broken down by NSW PHOs and quarter of the year: - Number of Applications - Number and percentage of applications approved within 90 days. - Number and percentage of applications with Research office processing time less than 45 days. - Average total time. - Average Research office processing days.

KPI21-04: Site-specific Assessment (SSA) Authorisation Timelines of Human Research Projects in NSW PHOs	Summary:	A summary of the all-NSW research governance review performance: total number of applications, clinical trials, and average total time.
	Table 6:	All greater than low risk site authorisation within the reporting period broken down by NSW PHOs: - Number of Applications. - Number and percentage of site application authorised within 60 days. - Average total time and average breakdown by the processing time of research office, CE, Head of Department, and researcher response time. - Count of requests for further information sent to researchers.
	Table 7:	All clinical trials site authorisation within the reporting period broken down by NSW PHOs: - Number of Applications. - Number and percentage of site authorisation approved within 60 days. - Average total time and average breakdown by the processing time of research office, CE, Head of Department, and researcher response time. - Count of requests for further information sent to researchers.
	Table 8:	Performances in clinical trial site authorisation broken down by sponsor type and NSW PHOs: - Number of Applications. - Average total time. - Average Research office processing days.
	Table 9:	All NSW performance in clinical trial site authorisation (greater than low risk) broken down by sponsor type and quarter of the year: - Number of Applications. - Average total time. - Average Research office processing days.
	Table 10:	Performance of NSW PHOs against the old and new benchmarks for site authorisations broken down by NSW PHOs and quarter of the year: - Number of Applications - Number and percentage of applications approved within 60 days. - Number and percentage of applications with Research office processing time less than 15 days. - Average total time. - Average Research office processing days.
Appendix 1 –	Note on Data Quality	A table noting data quality issues including any inconsistency in records arising from missing data/ error in REGIS that OHMR filled/corrected in its reporting dataset while preparing the Metrics Activity Report.

Dataset and Reporting Quality Control

To ensure the completeness of the dataset to facilitate accurate record-keeping and reporting, the research office, REGIS team and the OHMR team shares the responsibility of data quality control at each stage of the metrics reporting.

Quality Control Measure	Review Type	Data fields	Initially Entered/Generated by:	Data Quality Control Responsibility:
Completeness of Dataset pulled by OHMR from the back end of REGIS:	Ethics Application	Ethics Application Unique ID/ Reference	REGIS system generated	REGIS TEAM
		Decision Letter Sent Date	REGIS system generated	
		Study Status Change Time Stamp	REGIS system generated	
		Ethics Full Meetings Submission Closing Date	Research Office	Research Office
		Ethics Review Pathway	Researcher	
		Study Type	Researcher	
		Sponsor Type	Researcher	
		Current Study Status	Research Office Manual Change/ REGIS system generated according to workflow	REGIS TEAM & OHMR will enquire on unexpected manual study status changes for process improvement and data validation purposes.
		Study Status Change	Research Office Manual Change/ REGIS system generated according to workflow	
	Site Authorisation	Site Application Unique ID/ Reference	REGIS system generated	REGIS TEAM
		Decision Letter Sent Date	REGIS system generated	
		SSA Submission Date	REGIS system generated	
		Study Status Change Time Stamp	REGIS system generated	
		Does this SSA has a related Internal Ethics Approval in REGIS?	REGIS system generated	
		Internal Ethics Approval Date	REGIS system generated	
		External Ethics Approval Notification Upload Date	Researcher/RO upload the document. REGIS system generated	
		Ethics Review Pathway	Researcher	Research Office
		Study Type	Researcher	
		Sponsor Type	Researcher	

		Current Study Status	Research Office Manual Change/ REGIS system generated according to workflow	REGIS TEAM & OHMR will enquire on unexpected manual study status changes for process improvement and data validation purposes.
		Study Status Change	Research Office Manual Change/ REGIS system generated according to workflow	
REGIS Algorithm Reliability:	Ethics Application & Site Authorisation		REGIS system generated based on REGIS workflow and the above fields	REGIS TEAM & OHMR

To help the Research Office complete the data cleaning for the sites at the end of the 4 reporting period of each year, for each round of data cleaning, the OHMR team will be sending out three reminders for data cleaning in REGIS:

1. A generic reminder a week before the data cleaning deadlines,
2. Reminder to individual PHOs when we are generating the metrics results and identify errors/missing data points,
3. A table summarising any outstanding data points from all PHOs at the same time when we send the Metrics Activity Report for your final feedback before sending it to the CEs.

If the errors and missing data points were not all fixed in REGIS by the relevant PHOs before the formal release of the metrics activity report, a table noting data quality issues would be included. This table will include any inconsistency in records arising from missing data/ error in REGIS that OHMR filled/corrected in its reporting dataset while preparing the Metrics Activity Report.

If the errors and missing data point were corrected in REGIS before the release of the report, the appendix on data quality would be omitted from the Metrics Activity Report released.

APPENDIX 1: TERM DEFINITIONS (including some Data Field Definitions)

Clinical Trial	Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Clinical Trial Research Agreement (CTRA)	Clinical Trial Research Agreement (usually a standard template hosted by Medicines Australia) between Sponsor and Institution
Commercial Trial	A clinical trial where a commercial entity (often a pharmaceutical or device company), either on its own behalf or through a CRO: (a) Initiates the trial and i. makes an application to conduct the trial under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme administered by the Therapeutic Goods Administration; or ii. conducts an interventional phase IV study with prospective recruitment (e.g., excluding clinical practice audits and observational research with no active recruitment); and (b) Is directly funding the conduct of the trial, that is, making payments to the relevant hospital or investigator; and (c) Is the primary author or custodian of the clinical trial protocol
Contract Research Organisation (CRO)	A Contract Research Organization (CRO) is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
Coordinating Principal Investigator (CPI)	The individual who takes overall responsibility for the research project and submits the project for scientific and ethical review. The CPI is responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators.
Date first participant enrolled at site	Date first participant consented and screened, with eligibility verified. Often the date of randomisation, where applicable.
Date of HREC Approval	The date of the decision to approve on the HREC approval email (generated and e-mailed to the CPI or their delegate on the same day).
Date of Receipt of a SSA Application	The date that a fully signed SSA form is provided to the Research Governance Officer within an institution
HREC submission closing date	The last date an application for HREC approval can be submitted to be reviewed at the next meeting.
Internally Sponsored Clinical Trial	A clinical trial where a NSW institution has accepted the role of sponsor
Progress Reports	A report provided to the institution to enables appropriate study oversight
Final Progress Report	A report provided to the HREC at the time of Study Close
Registry	A structured online system, such as ClinicalTrials.gov, that provides the public with access to summary information about ongoing and completed clinical studies.
Site Initiation Visit (SIV)	The on-site/telephone meeting designed to prepare the study team for conducting the study.

Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. For non-commercial trials, the sponsor is often the employer of the Co-ordinating Principal Investigator.
Study Close	The study has finished normally at the site and participants are no longer being treated or examined (last patient, last visit)
Study Completion	The final date on which data was (or is expected to be) collected (i.e., The time point when data analysis can begin).
Final Study Report	A full study report of trial results detailing methods, analysis, results, and conclusions of a clinical trial and complying with the CONSORT Statement (or when applicable, CONSORT Extensions).
Summary Results Report	A report of clinical trial summary results posted publicly where the trial was registered (or if not possible within the registry, in another location) within one year of the completion of the trial. Reports of clinical trial summary results should at least contain the items on a clinicaltrials.gov results page.
Final Study Report	A final report for the study that complies with the 25-item CONSORT statement on trial reporting providing detailed information about the methods, analysis, results and conclusions of a clinical trial.
The CONSORT Statement	An evidence-based, minimum set of recommendations for reporting randomized trials. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.
The SPIRIT Statement	The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials): An international initiative that aims to improve the quality of clinical trial protocols by defining an evidence-based set of items to address in a protocol. Provides high-quality standards for trial protocols, helping to streamline their development and reporting.
Trial Registration	The process of submitting and updating summary information about a clinical study protocol, from its beginning to end, to a structured, Web-based registry that is accessible to the public, such as ClinicalTrials.gov.
Trial restart date	The date enrolment of participants to the study is re-started following a temporary suspension.
Trial suspension date	Enrolment of participants to the study at the site has been halted but may resume at a future date.
Trial termination date	The study has been stopped prematurely or abandoned and will not reopen.
Trial withdrawn date	The study stopped early, before ethics approval or site authorisation were granted.
Valid Reason For Not Meeting Target	Generally, reasons for not meeting the target are valid because they are: • Outside the control of the HREC/institution/site (e.g. sponsor delay) • Recognised up front as a possible extenuating circumstance (e.g. rare disease condition where enrolment is hard to predict) • An unforeseen or unavoidable event

APPENDIX 2: DIAGRAM FOR REGIS WORKFLOW AND METRIC 3 & 4 (MONITORING METRICS) CALCULATIONS.

Metric 3 Ethics - REGIS Workflow

Legends:

Green Arrow: Workflow;

Blue Arrow: Algorithm.

Process

Decision

Days Accruel Start

Days Accruel Stop

Interim Calculation

Result Reported as Metrics

Start

The researcher will have to re-start the application from the start of the workflow

If an application is withdrawn by the applicant/ the Research Officer at any point before the approval is granted.

Not Reportable for M3

Ethics Application Initially Submitted by Researchers

Research Office Decision on Eligibility

Is this application eligible for review?

No

Yes

Application Returned to Researcher to resubmit

Researcher Re-submit the application

M3 Researcher breakdown Stop

Actual days accrued when application is with researcher:
researcher breakdown Stop - researcher breakdown Stop

If more than one period the application is sent to reseracher to amend or resubmitt (*n* periods):
(Researcher breakdown Stop 1 - Researcher breakdown Start 1) + (Research breakdown Stop 2 - Researcher breakdown Start 2) + ... + (Researcher breakdwon Stop *n* - Researcher breakdown Start *n*)

M3 Researcher breakdown Start

The researcher breakdown days reported are to take into consideration the M3 counting start date, and ignore the days accrued before that date.

Researcher Breakdown time reported

M3 RO Breakdown Start

M3 RO Breakdown Stop

Actual days accrued when application is with research office:
research office breakdown Stop - research office breakdown Stop

If more than one period the application is resubmitted to the RO to review (*n* periods):
(Research office Stop 1 - Research office Start 1) + (Research office Stop 2 - Research office Start 2) + ... + (Research office Stop *n* - Researcher office Start *n*)

M3 RO Breakdown Start

The research office breakdown days reported are to take into consideration the M3 counting start date, and ignore the days accrued before that date.

Research office Breakdown time reported

Researcher provide information requested

Review by Research Office

will this application go to a full HREC meeting?

Yes

Assign to a meeting

No

Ethics Meeting

M3 Counting Start: Initial full HREC Meeting submission closing date

M3 total time: M3 counting stop - M3 Counting Start

M3 Counting Stop

Does this application need further information from researchers (request for further info)

Application returned to researcher for response

Yes

No

M3 RO Breakdown Stop

Decision Notification

Was the application approved?

No

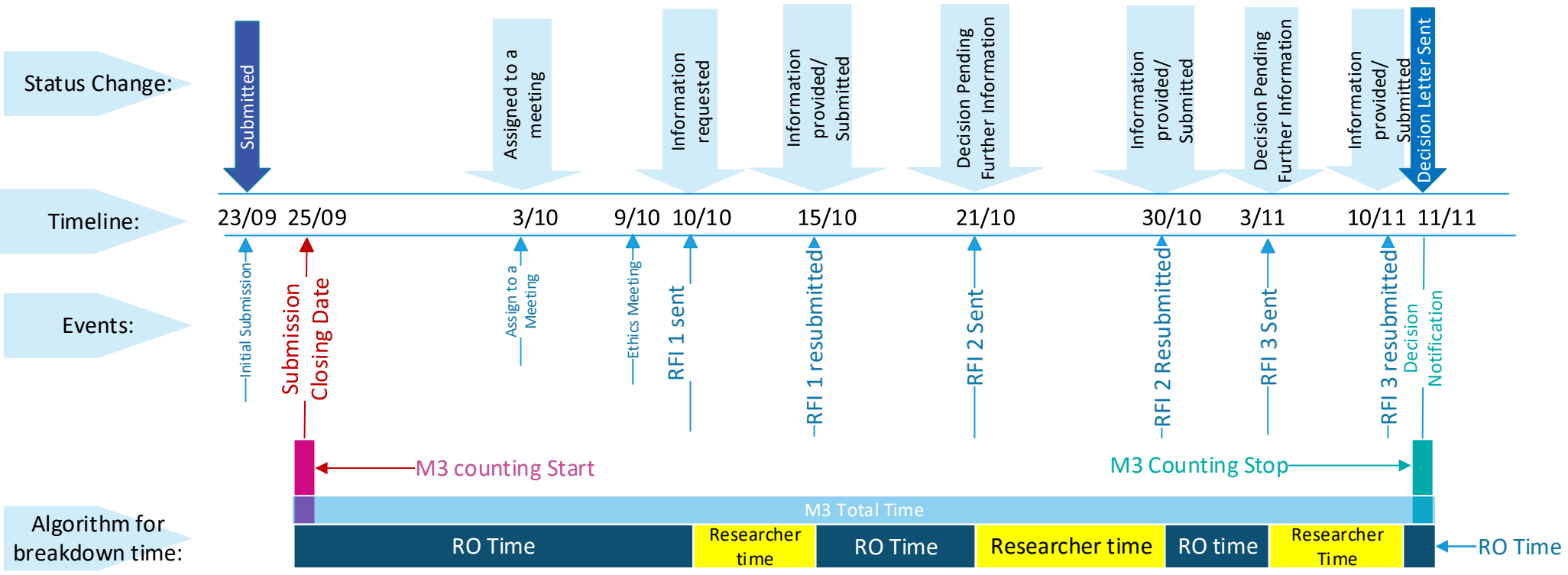
Not Reportable for M3

Yes

Reportable for M3

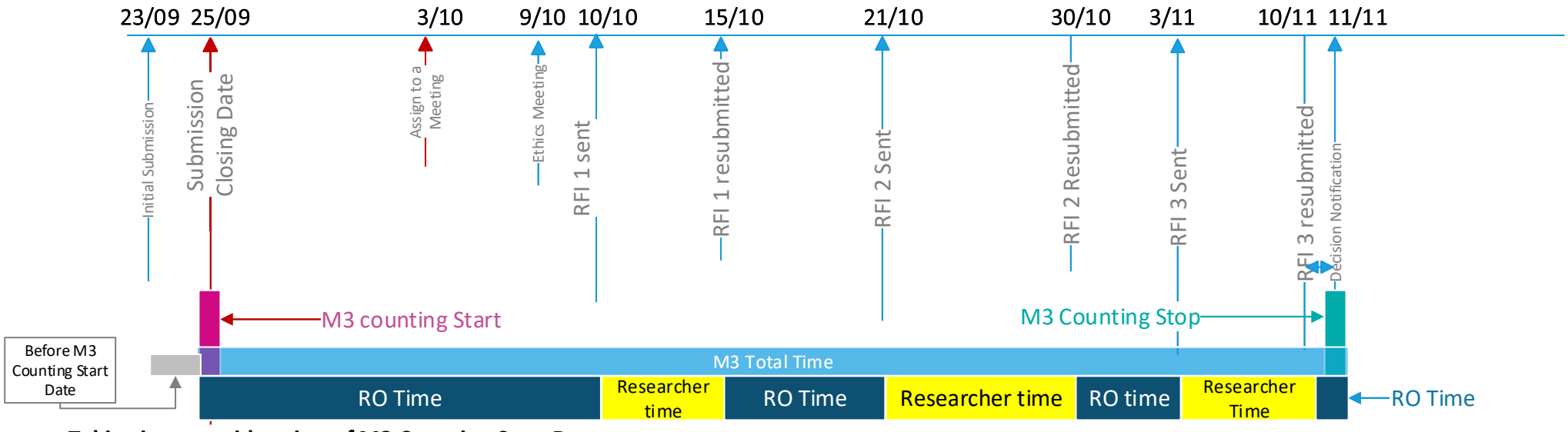
STOP

Example timeline for Calculating M3 Research Office Breakdown (blue is RO time, yellow is researcher's (Rr) time, RFI = request for further information)



M3 RO Breakdown time will account for the Submission Closing Date for the Initial Ethics Meeting the application is tabled at, "M3 Counting Start" date, which may fall on a date during or after the first RO period

Scenario 1: M3 Couting start date is within the first RO period (RO1)



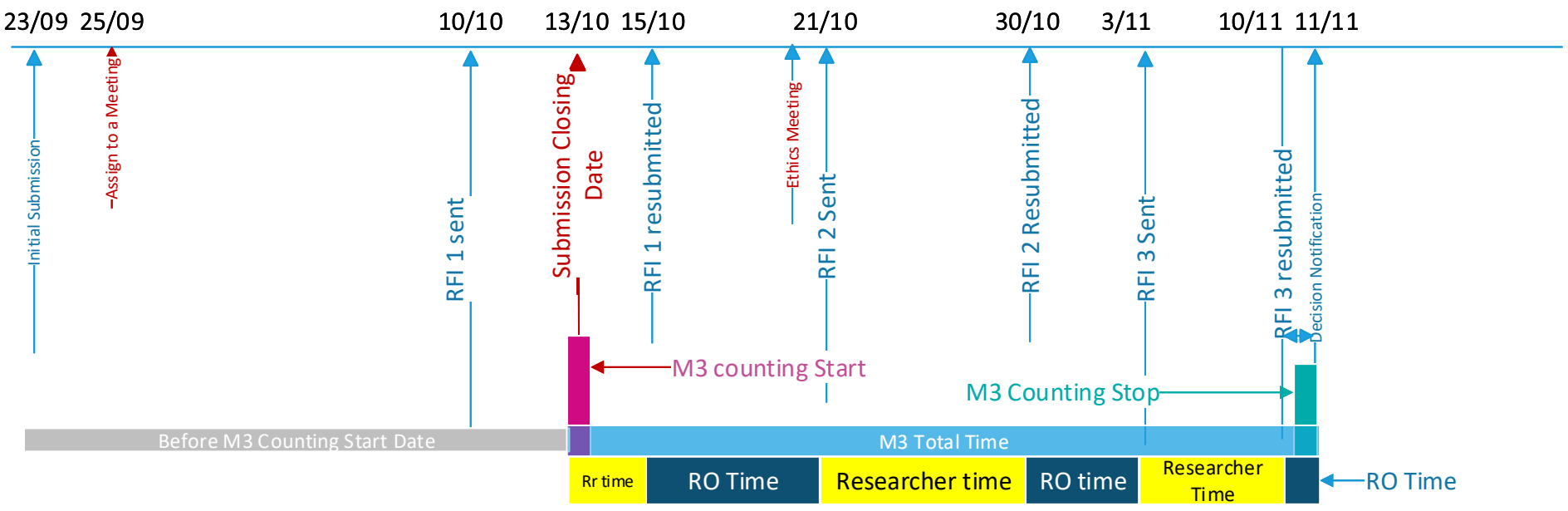
Taking into consideration of M3 Counting Start Date:

M3 total time = M3 counting stop - M3 counting start = 11/11 - 25/09 = 47 days

M3 RO breakdown days = (RO1 stop - M3 counting start) + (RO2 Stop - RO2 Start) +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 15+6+4+1 = 26 days

M3 Researcher breakdown days = (Rr1 stop - Rr1 start) + (Rr2 stop - Rr1 start) + (Rr3 Stop - Rr3 Start) = 5 +9+7 = 21 days

Scenario 2: M3 Couting start date falls in the gap between RO1 and RO2 periods.



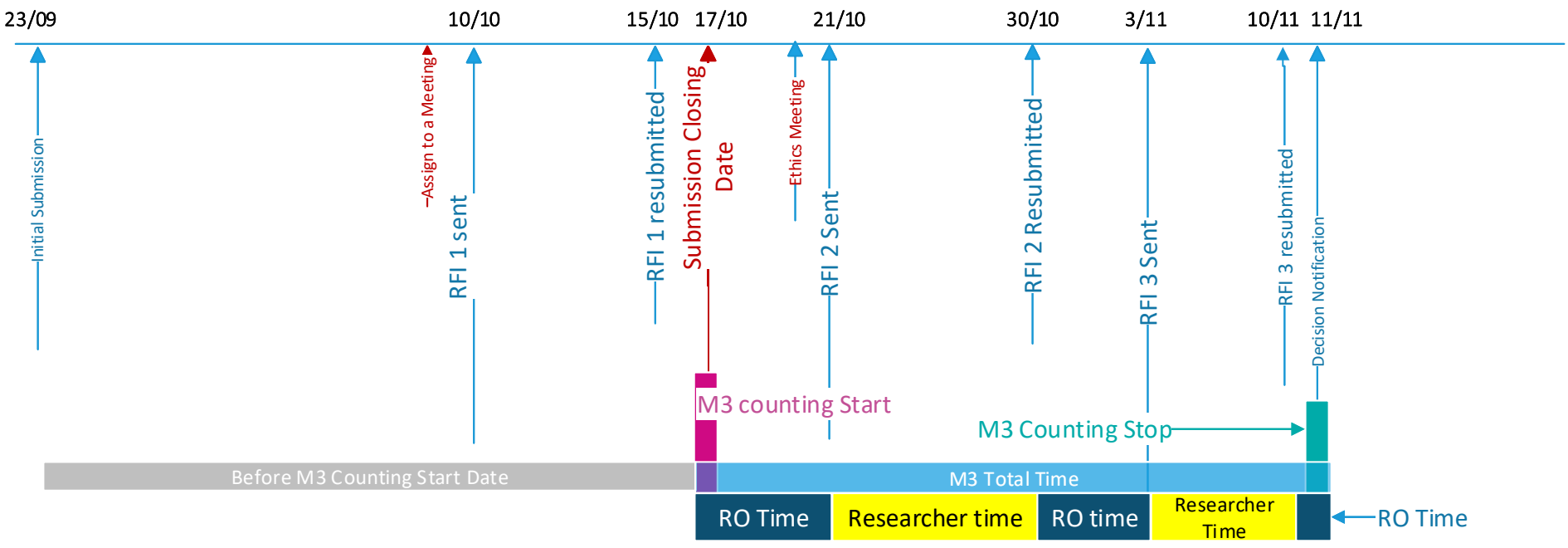
Taking into consideration of M3 Counting Start Date:

M3 total time = M3 counting stop - M3 counting start = 11/11 - 13/10 = 29 days

M3 RO breakdown days: 0 (RO1 period should not be counted)+ (RO2 Stop - M3 Start Date) +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 0+6+4+1 = 11 days

M3 Researcher breakdown days = (Rr1 stop -M3 counting start) + (Rr2 stop - Rr2 start) + (Rr3 Stop - Rr3 Start) = 2 +9+7 = 18 days

Scenario 3: M3 Couting start date falls within the second RO period (RO2)



Taking into consideration of M3 Counting Start Date:

M3 total time = M3 counting stop - M3 counting start = 11/11 - 17/10 = 25 days

M3 RO breakdown days: 0 (RO1 period should not be counted)+ **(RO2 Stop - M3 Counting Start)** +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 0+4+4+1 = 9 days.

M3 Researcher breakdown days = 0+ (Rr2 stop - Rr2 start) + (Rr3 Stop - Rr3 Start) = 0 +9+7 = 16 days

Metric 4 Governance (Site Specific Assessment) - REGIS Workflow

Legends:

Green Arrow: Workflow;

Blue Arrow: Algorithm.

Process | Days Accruel Start | Interim Calculation

Decision | Days Accruel Stop | Result Reported as Metrics

Start

SSA Application Initially Submitted by Researcher

Is the related Ethics Review Within REGIS?

YES → Was Ethics Approval granted before SSA submission

YES → M4 Counting Start: from the SSA Submission Date

NO → Ethics Approval Granted in REGIS → M4 Counting Start: from the Ethics Approval Granted Date

NO → Ethics Approval Letter uploaded by Researcher → M4 Counting Start: from the Approval Letter upload time

HOD added by researcher?

No → RGO Review → RO Breakdown Start

Yes

Send to Researcher to add HOD → RO Breakdown Stop

HOD Review → HOD breakdown Start

HOD Makes Decision → HOD breakdown Stop

Actual days accrued when application is with a Head of Department:
HOD breakdown Stop - HOD breakdown Stop

If more than one period the application is resubmitted to the RO to review (*n* periods):
(HOD Stop 1 - HOD Start 1) + (HOD Stop 2 - HOD Start 2) + ... + (HOD Stop *n* - HOD Start *n*)

The HOD breakdown days reported are to take into consideration the M4 counting start date, and ignore the days accrued before that date.

HOD Breakdown time reported

HOD Approves

No → Researcher amend application/ add HOD → New HOD Added/ HOD not supported → Researcher breakdown Start

YES → RGO Review → Once HOD Approved/ commented, used to change to pending submission and then submission → RO Breakdown Start

RGO make a decision → RO sent to Researcher RFI, to HOD review, or to CE sign-off → RO Breakdown Stop

Does this application need further review by HOD/ another HOD

YES → ask the Researcher to add a new HOD → Researcher re-submit the application → Researcher breakdown Stop

Actual days accrued when application is with researcher:
researcher breakdown Stop - researcher breakdown Stop

If more than one period the application is sent to reseracher to amend or resubmit (*n* periods):
(Researcher breakdown Stop 1 - Researcher breakdown Start 1) + (Research breakdown Stop 2 - Researcher breakdown Start 2) + ... + (Researcher breakdwon Stop *n* - Researcher breakdown Start *n*)

The Researcher breakdown days reported are to take into consideration the M4 counting start date, and ignore the days accrued before that date.

Researcher Breakdown time reported

No → RGO Review → Researcher Resubmit for review → RO Breakdown Start

Actual days accrued when application is with research office:
research office breakdown Stop - research office breakdown Stop

If more than one period the application is resubmitted to the RO to review (*n* periods):
(Research office Stop 1 - Research office Start 1) + (Research office Stop 2 - Research office Start 2) + ... + (Research office Stop *n* - Researcher office Start *n*)

The research office breakdown days reported are to take into consideration the M4 counting start date, and ignore the days accrued before that date.

Research office Breakdown time reported

Researcher amend application → RO requesting further info → Researcher breakdown Start

YES → Does this application need further information from researchers

No → RGO recommendations to the CE → CE Breakdown Start

Actual days the application sits with CE:
M4 CE breakdown Stop - M4 CE breakdown Stop → Reported as CE breakdown time

CE decision made → CE Breakdown Stop

Was the application authorised?

No → Not Reportable for M4

Yes → Reportable for M4

RGO create notification email → CE made a deicision and decision email is to be drafted → RO Breakdown Start

RGO send Decision Notification Email → RO Breakdown Stop

STOP

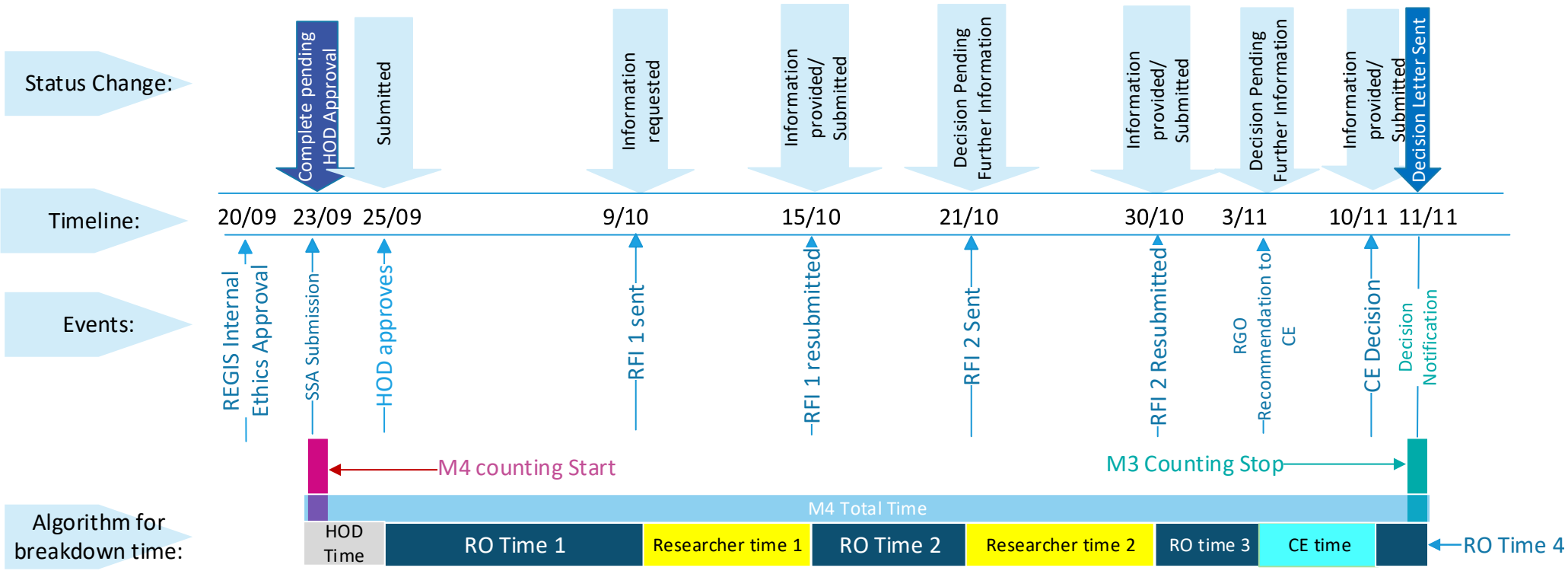
M4 Counting Stop

M4 total time: M4 counting stop - M4 Counting Start

If an application is withdrawn by the applicant/ the Research Officer at any point before the authorisation is granted. → Not Reportable for M4

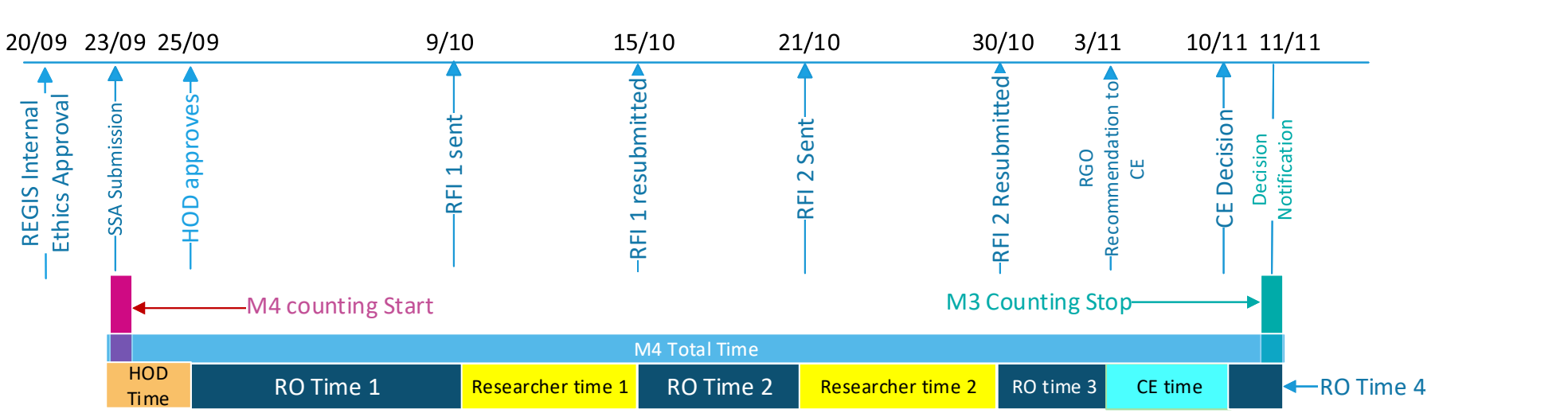
The researcher will have to re-start the application from the start of the workflow

Example timeline for Calculating M4 HOD, Researcher, Research Office Breakdown (RFI = request for further information)



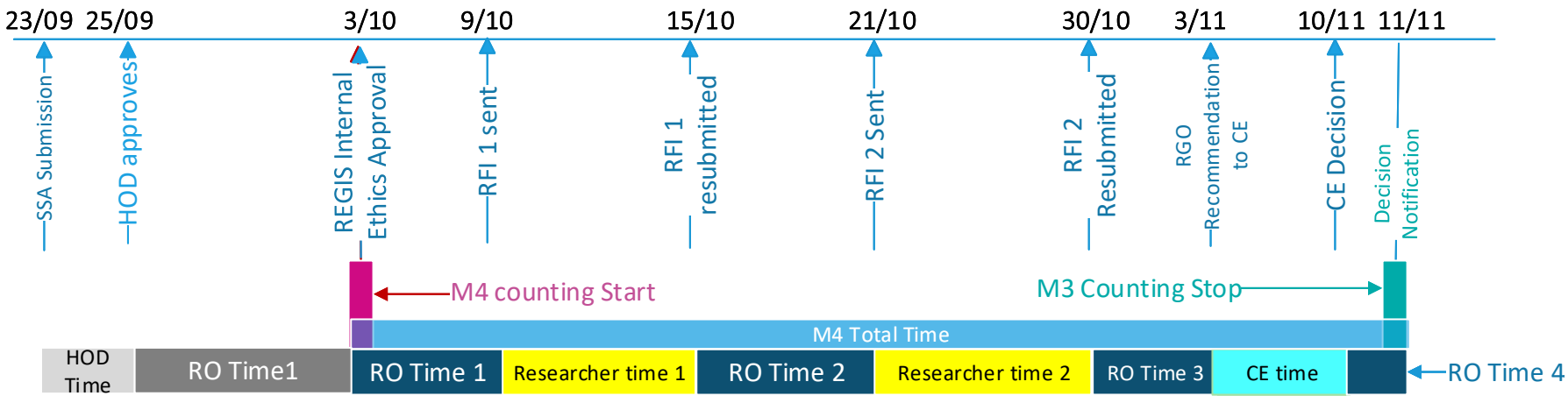
HOD, Researcher, Research Office Breakdown time will account for the "M4 Counting Start" date. Take the calculation of Research Office time as an example, the M4 Counting Start date may fall on a date before, during or after the first RO period.

Scenario 1: M4 Couting start date is **before** the first RO period (RO1)



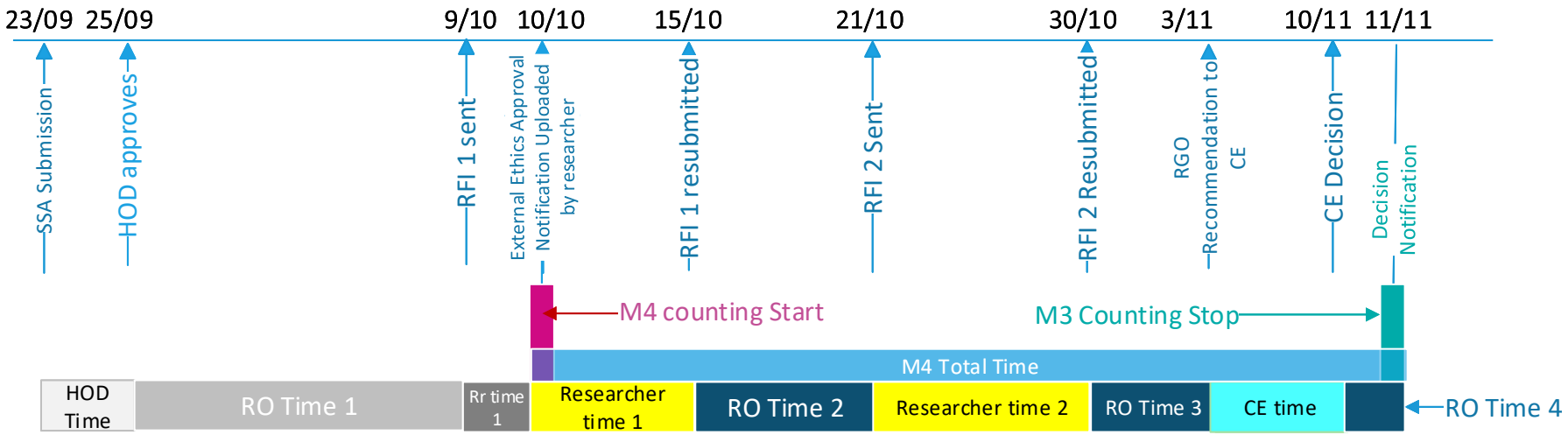
Taking into consideration of M4 Counting Start Date:
M4 total time = M4 counting stop - M4 counting start = 11/11 - 23/09 = 49 days
RO breakdown days = (RO1 stop - RO1 Start) + (RO2 Stop - RO2 Start) +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 14+6+4+1 = 25 days
HOD Time = 2 days.
CE time = 10/11 - 3/11 = 7 days.
Researcher time = (Rr1 Stop - Rr1 Start) + (Rr2 Stop - Rr2 Start) = 6+9 =15 days.

Scenario 2: M4 Couting start date is **within** the first RO period (RO1)



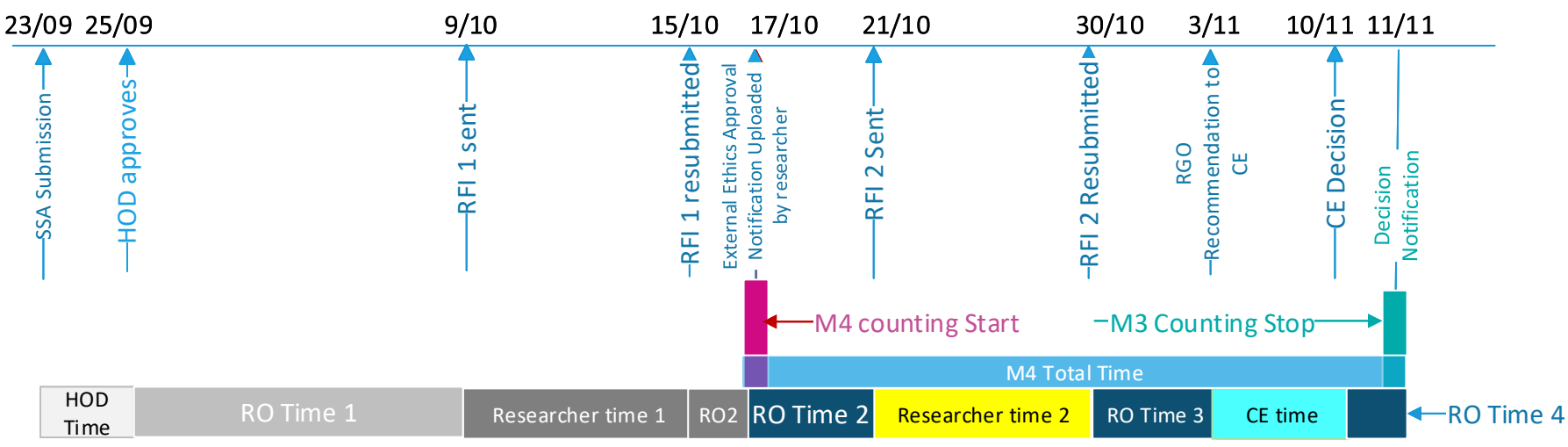
Taking into consideration of M4 Counting Start Date:
M4 total time = M4 counting stop - M4 counting start = 11/11 - 03/10 = 39 days
RO breakdown days = (RO1 stop - M4 counting start) + (RO2 Stop - RO2 Start) +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 6+6+4+1 = 17 days
HOD Time = 0 days. As M4 counting start date falls after the HOD period.
CE time = 10/11 - 3/11 = 7 days.
Researcher time = (Rr1 Stop - Rr1 Start) + (Rr2 Stop - Rr2 Start) = 6+9 =15 days.

Scenario 3: M4 Couting start date falls in the gap between the first and second RO period (RO1, RO2)



Taking into consideration of M4 Counting Start Date:
M4 total time = M4 counting stop - M4 counting start = 11/11 - 10/10 = 32 days
RO breakdown days = 0 (RO1 Period is before M4 counting start) + (RO2 stop - RO2 start) +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 0+6+4+1 = 11 days
HOD Time = 0 days. As M4 counting start date falls after the HOD period.
CE time = 10/11 - 3/11 = 7 days.
Researcher time = (Rr1 Stop - M4 Counting Start) + (Rr2 Stop - Rr2 Start) = 5+9 =14 days.

Scenario 4: M4 Couting start date falls during the second RO period (RO2)



Taking into consideration of M4 Counting Start Date:
M4 total time = M4 counting stop - M4 counting start = 11/11 - 17/10 = 25 days
RO breakdown days = 0 (RO1 Period is before M4 counting start) + (RO2 stop - M4 Counting Start) +(RO3 Stop - RO3 Start) +(RO4 Stop - RO4 Start) = 0+4+4+1 = 9 days
HOD Time = 0 days. As M4 counting start date falls after the HOD period.
CE time = 10/11 - 3/11 = 7 days.
Researcher time = 0 (Rr1 Period is before M4 counting start) + (Rr2 Stop - Rr2 Start) = 0+9 =9 days