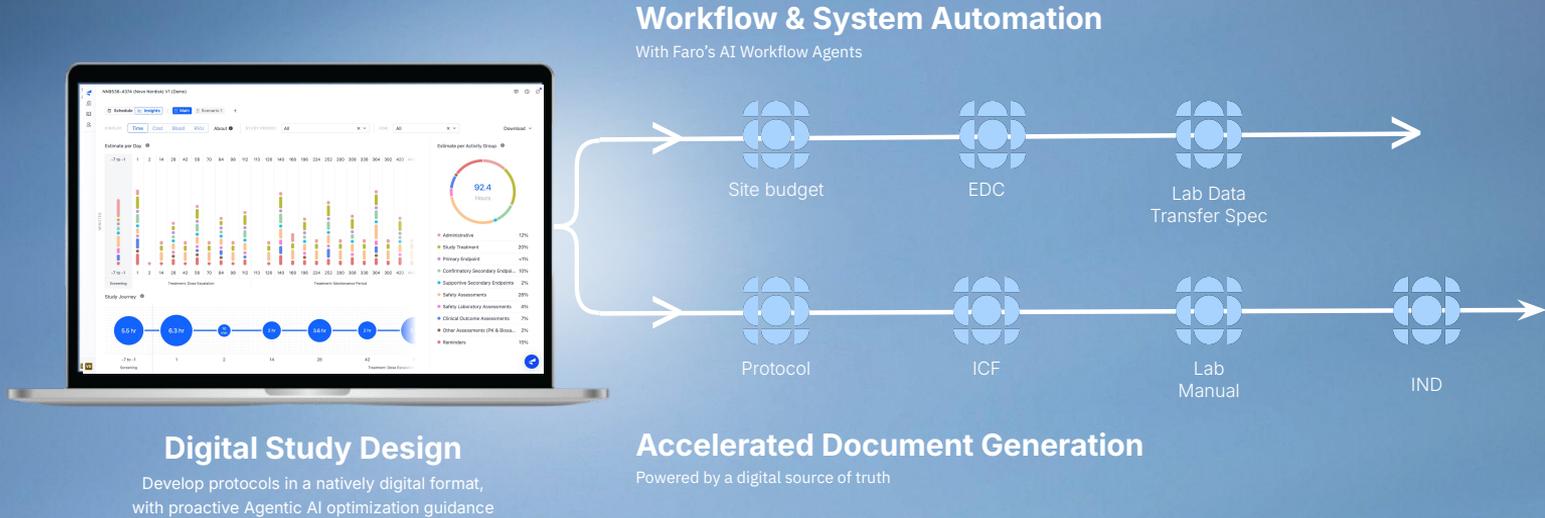


Accelerating Digital Data Flow Journey with Faro

Faro provides the data-driven foundation for automation

With Faro, sponsors save significant time and cost while simultaneously improving quality



Connected by Standards

LOINC

- Code: [34529-8](#)
- Represents the lab panel identifier used across labs
- Includes component tests such as PT, aPTT and INR

SNOMED

- Code: [3116009](#) Blood coagulation panel (procedure)
- Captures the procedure context that a panel of a coagulation related test is performed



- Code: [85610](#) - Prothrombin time/INR
- Code: [85730](#)- Thromboplastin time, partial (PTT)
- Provides billing/operational codes and RVU for the individual tests within the panel



USDM ensures that study definitions are structured, machine-readable, and vendor-neutral enabling seamless interoperability and end-to-end digital data flow.



- Class: Findings
- Domain: LB
- Variable: LBTESTCD, LBTEST, LBORRESU, LBRESSCL, LBRESTYP, LBSTRESC, LBSPEC, LBLOINC
- Ensures regulatory submission compliance across all panel components



- Codelist: LBTEST/LBTESTCD
- Standardize component lab tests using submission value or NCI preferred term
 - NCI Terminology: [C62656](#) - Prothrombin Time
 - NCI Terminology: [C187818](#) - PTT/Standard



- BC bundles the definition, component concepts, values, metadata (range, result type, timing, specimen) and crosswalk
- Value: Instead of manually assembling each test and metadata, BC provides ready to use, standards aligned block

| Week | Day | Visit Label | Visit Window | Cycle 1 30 days, 1 cycle | | | | | | | |
|--------------------------------------------------------------------|----------------------|-------------|--------------|-----------------------------|------|------|------|------|------|-----|-----|
| | | | | Site | Site | Site | Site | Site | Site | | |
| ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... | ... |
| Laboratory Assessments | | | | | | | | | | | |
| Chorionicotropin (Pregnancy Test) [Presence], Serum | Serum | 1 | | | | | | | | | |
| CBC W Differential Panel by Unspecified Method, Blood | Blood | 2 | | | | | | | | | |
| Blood Smear Finding by Light Microscopy, Blood | Blood | 2 | | | | | | | | | |
| Comprehensive Chemistry Panel, Serum | Serum | 3 | | | | | | | | | |
| Urate [Mass/Vol], Serum | Serum | 3 | | | | | | | | | |
| Phosphate [Mass/Vol], Serum | Serum | 3 | | | | | | | | | |
| Haptoglobin [Mass/Vol], Plasma | Plasma | 2 | | | | | | | | | |
| Fibrin D-Dimer DDU [Mass/Vol], Platelet poor plasma | Platelet poor plasma | 2 | | | | | | | | | |
| Thrombin Time, Platelet poor plasma | Platelet poor plasma | 2 | | | | | | | | | |
| Fibrinogen [Mass/Vol] by Coagulation assay, Platelet poor pl... | Platelet poor plasma | 2 | | | | | | | | | |
| Coagulation Panel (PT/INR, aPTT), Platelet poor plasma | Platelet poor plasma | 1-1 | | | | | | | | | |
| ABO Group [Type], Blood | Blood | | | | | | | | | | |
| Direct Antigen Globulin Test, Direct Coombs (Presence), Red Blo... | Red Blood Cells | | | | | | | | | | |
| Urinalysis Macro Panel by Dipstick, Urine | Urine | 2 | | | | | | | | | |
| Analyzed Sample, Plasma | Plasma | 4 | | | | | | | | | |
| CD47 Receptor Occupancy, Blood | Blood | 5 | | | | | | | | | |

Faro Product Suite - Aligned with Standards



AI Powered Trial Ingestion Pipeline

Protocol Import converts unstructured protocol documents into structured, **USDM**-aligned study data through **activity matching** within the Faro BCL and alignment with external standards.



TransCelerate



Protocol Optimization

Leverages structured definition model to analyze design consistency and completeness in accordance with **TransCelerate** and **Tufts CSDD** Framework



Faro Authoring

Leverages structured study data to ensure alignment with **ICH M11**



Faro API

Enables **automated EDC study build** directly from **USDM**-aligned digital protocol definitions and underlying **Biomedical Concepts (BC)**

Faro
Protocol Import / ex611816.pdf
Import to Study Definition

Study Spaces

Protocol Import

Protocol Optimization

ex611816.pdf

Welcome! I'm here to help you quickly import your study protocol into your workspace.

ex611816.pdf

Study Periods Version 1

Activity Matching Version 1

Import summary

Import summary

Import Summary

Here is what was processed

- 7 study period identified (18 day total)
- 38 activities created for the library activities
- 3 placeholders created for unmatched activities
- 179 scheduling rules generated

Ready for Import

The extracted study periods, matched activities, and generated schedule rules are ready to be imported into your study protocol. Please review the details above and confirm to proceed with the import.

- Edit in the Study Designer
- Configure placeholder activities
- Add additional rules or modifications as needed

Chat with us

Maxine Chan

Chat is archived. You may review all generated artifacts and conversation history, but modifications are no longer possible.

Faro | Faro USDM Hub

Upload Start over Compare CORE rules

Original **Tree view** Search in data... Expand all Collapse all Export CSV Export JSON

```

root: { 4 properties }
study: { 8 properties }
id: "5b487280-d9bc-44ad-b624-da47529b68aa"
name: "EX611816 Solid Tumor"
description: "A Phase 1b/2 Open-Label Study of the Efficacy and Safety of Etigilimab (MPH313) Administered in Combination w
label: "null"
extensionAttributes: []
versions: [ 1 items ]
[0]: { 28 properties }
id: "StudyVersion_1"
extensionAttributes: []
versionIdentifier: "1.0"
rationale: "A Phase 1b/2 Open-Label Study of the Efficacy and S
+ documentVersionIds: [ 1 items ]
+ dateValues: [ 1 items ]
amendments: []
+ studyIdentifiers: [ 2 items ]
+ businessTherapeuticAreas: [ 1 items ]
+ studyInterventions: [ 1 items ]
+ titles: [ 2 items ]
+ organizations: [ 1 items ]
+ roles: [ 1 items ]
    
```

CORE Rules Validation ✕

CORE Rules Summary

| | | |
|----------------------|---------------------------|-----------------------|
| 205 PASSED | 39 NEEDS REVIEW | 11 WARNINGS |
|----------------------|---------------------------|-----------------------|

Data Structure Overview ✔ Passed

General Rules (7 rules) ⚠ NeedsReview

Study Version (7 rules) ✔ Passed

Study Design (36 rules) ⚠ NeedsReview

Study Identifiers (3 rules) ⚠ NeedsReview

Faro

- Study Spaces
- Protocol Import
- Protocol Optimization
- EX611816 - CDISC Webinar Version
- Study Framework
 - Overall Design Summary
 - Study Interventions
 - Activity Configuration
 - Statistical Considerations
- Study Definition
 - EX611816-01 Solid Tumor...
 - Objectives and Endpo...
 - Population Summary
 - Inclusion Criteria
 - Exclusion Criteria
 - Study Design
 - Import
- Data
 - Insights
 - Compare
- Chat with us
- Maxine Chan

EX611816-01 Solid Tumor (v2)

Insights Filter Search for activities by name

Notes Legend

| | -1 | ← Day 0 → | | | | 14 | 28 | 42 | 56 | 70 | | | | | | | | | |
|------------------------------|--------------------------|---------------------------------------------------------------------|------|------|----|-----------------------------------------------------------|------|----------------------------------------------------------|------|-----------------------------------------------------------|----|----------------------------------------------------------|----|----------------------------------------------------------------------------|----|------|----|------|----|
| | Screening Study... 1 day | Cycle 1 Study Days 1-8, representing the first treatment... 14 days | | | | Cycle 2 Study Days 15-22, the second treatment... 14 days | | Cycle 3 Study Days 29-36, the third treatment... 14 days | | Cycle 4 Study Days 43-50, the fourth treatment... 14 days | | Cycle 5 Study Days 57-64, the fifth treatment... 14 days | | Cycle 6 And Beyond Study Day 71 onwards, where standard of care... 14 days | | | | | |
| Week | -1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | | | | | |
| Day | -1 | 1 | 3 | 8 | 14 | 15 | 21 | 28 | 29 | 35 | 42 | 43 | 49 | 56 | 57 | 70 | 71 | 77 | 84 |
| Visit Label | | | | | | | | | | | | | | | | | | | |
| Visit Window | | | | | | | | | | | | | | | | | | | |
| Locations | Site | Site | Site | Site | | Site | Site | | Site | Site | | Site | | Site | | Site | | Site | |
| Medical History | | | | | | | | | | | | | | | | | | | |
| Subsequent Cancer Therapies | | | ● | | ● | | | | | | | | | | | | | | |
| Medical History | 1 | ● | ● | | | | | | | | | | | | | | | | |
| Concomitant Medications | 2 | | ● | ● | ● | | | ● | ● | | | | | | | | | | |
| Medical History | 1 | ● | ● | ● | | | | | | | | | | | | | | | |
| Body Temperature | | | ● | | | | | | | | | | | | | | | | |
| Physical Assessments | | | | | | | | | | | | | | | | | | | |
| Cancer Assessment | 1 | ● | | | | | | | | | | | | | | | | | |
| Vital Signs | 3 | | ● | ● | ● | | | ● | ● | | | | | | | | | | |
| Complete Physical Exam | 4 | ● | | | | | | | | | | | | | | | | | |
| Targeted Physical Exam | | | ● | | ● | | | ● | ● | | | | | | | | | | |
| Body Height | | ● | | | | | | | | | | | | | | | | | |
| Body Weight | 5 | ● | ● | ● | ● | | | ● | ● | | | | | | | | | | |
| 12 Lead ECG | 6 | ● | ● | | | | | | | | | | | | | | | | |
| Administrative | | | | | | | | | | | | | | | | | | | |
| Demographics | 1 | ● | | | | | | | | | | | | | | | | | |
| Survival Status | | | | | | | | | | | | | | | | | | | |
| Informed Consent Form | 7 | ● | | | | | | | | | | | | | | | | | |
| Inclusion/Exclusion Criteria | | ● | | | | | | | | | | | | | | | | | |
| Clinical Labs | | | | | | | | | | | | | | | | | | | |
| Chemistry Panel | Serum 8 | ● | ● | | ● | | | ● | ● | | | | | | | | | | |
| Chemistry Panel | Serum 8 | ● | ● | | ● | | | ● | ● | | | | | | | | | | |
| Thyrotropin (TSH) [Unit/Vol] | Serum 9 | ● | ● | | | | | | | ● | | | | | | | | ● | |

Faro

- Study Spaces
- Protocol Import
- Protocol Optimization

EX611816 - CDISC Webinar Version

Study Framework

- Overall Design Summary
- Study Interventions
- Activity Configuration
- Statistical Considerations

Study Definition

- EX611816-01 Solid Tumor (v2)
 - Objectives and Endpoi...
 - Population Summary
 - Inclusion Criteria
 - Exclusion Criteria
 - Study Design
 - Import

Data

- Insights**
- Compare

Chat with us

Maxine Chan

EX611816-01 Solid Tumor (v2)

Metric: **Participant Time** | Schedule: **Import** | Time Range: **Entire Study**

[Schedule](#) [Insights](#) [Download](#)

Participant Time

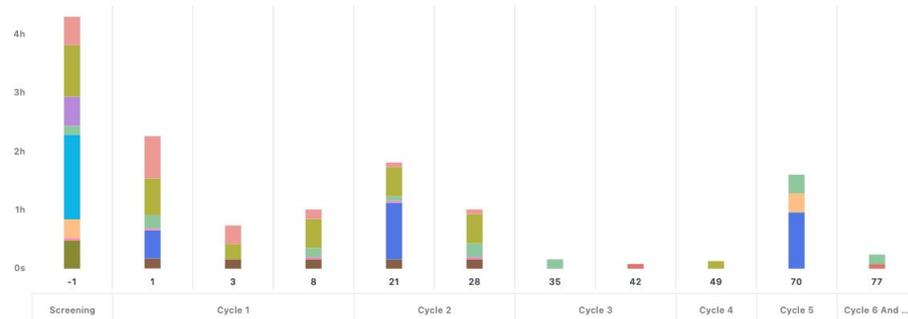
The data represented are estimates using average activity durations for each activity in your schedule. [Learn More](#)

The charts below group identical days that appear adjacent in the schedule of activities, showing only one instance per group.

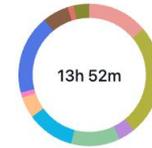
Study Journey



Participant Time per Activity Group



Estimated Participant Time by activity group



- Include optional activities
- Medical History: 1h 55m
- Physical Assessments: 3h 31m
- Administrative: 31m
- Clinical Labs: 1h 34m
- Imaging: 1h 30m
- Clinical Evaluation: 40m
- Clinician-Reported Outcomes (CI...): 10m
- Study Treatment: 2h 30m
- Safety Reporting: 50m
- Genomic Labs: 11m
- Future Use / Biobanking: 30m

Faro
EX611816-01 Solid Tumor (v2)
🔍 🕒 ↺

Compare

■ Primary EX611816-01 Solid Tumor (v2)
■ Comparison 5F9004-Phase 1b

Schedule: Import
Main

Time Range: Entire Study
Entire Study

Include Optional Activities
 Download

Participant Time

The data represented are estimates using average activity durations for each activity in your schedule. [Learn More](#)

Total Time per Participant

↓ **60h 26m**

■ Primary: 13h 52m
■ Comparison: 74h 18m

Participant Time per Scheduled Day

↓ **1h 8m**

■ Primary: 1h 16m
■ Comparison: 2h 24m

Total Scheduled Days

↓ **20**

■ Primary: 11
■ Comparison: 31

| Grouped Data Table | ■ Primary | | ■ Comparison | | Data Format | Percentage |
|-----------------------------------------------------------------------------------------------------------|----------------|---------|----------------|---------|-------------|------------|
| | Activity Count | Time | Activity Count | Time | | |
| Clinical Data Type 🔍 1☰ <input checked="" type="checkbox"/> Total for selected activities | | 13h 52m | | 74h 18m | | 60h 26m ↓ |
| <input checked="" type="checkbox"/> Administrative | | 4% | | <1% | | 3% ↑ |
| <input checked="" type="checkbox"/> Medical History | | 13% | | 4% | | 10% ↑ |
| <input checked="" type="checkbox"/> Physical Assessments | | 26% | | 24% | | 2% ↑ |
| <input checked="" type="checkbox"/> Clinical Evaluation | | 5% | | 5% | | <1% ↓ |
| <input checked="" type="checkbox"/> Study Treatment | | 18% | | 36% | | 18% ↓ |
| <input checked="" type="checkbox"/> Imaging | | 11% | | — | | 11% ↑ |
| <input checked="" type="checkbox"/> Clinical Labs | | 11% | | 4% | | 7% ↑ |
| <input checked="" type="checkbox"/> Genomic Labs | | 1% | | 1% | | <1% ↑ |
| <input checked="" type="checkbox"/> Pharmacokinetic / Pharmacodynamic (PK/PD) | | — | | 2% | | 2% ↓ |
| <input checked="" type="checkbox"/> Future Use / Biobanking | | 4% | | — | | 4% ↑ |
| <input checked="" type="checkbox"/> Safety Reporting | | 6% | | 7% | | <1% ↓ |
| <input checked="" type="checkbox"/> Clinician-Reported Outcomes (ClinRO) | | 1% | | <1% | | <1% ↑ |
| <input checked="" type="checkbox"/> Logistics | | — | | 17% | | 17% ↓ |
| <input checked="" type="checkbox"/> Wait | | — | | 32 | | 17% ↓ |

Faro

- Study Spaces
- Content Library
- User Management
- Protocol Import
- Protocol Optimization**

BP30037

Chat with us
Maxine Chan

Protocol Optimization / BP30037

Welcome! I'm here to help make your study design as efficient, cost effective, and participant-centered as possible.

My Role

I help you evaluate and refine your study definition so that it is complete, efficient, and aligned with best practices. By benchmarking your protocol against the Tufts CSDD Framework, I provide data-driven insights to help reduce cost, improve operational feasibility, and minimize participant burden.

What to Expect

1. Validate – I'll check whether your study definition is complete and ready for optimization.
2. Analyze – I'll compare your study design against the Tufts CSDD Framework benchmarks.
3. Optimize – I'll highlight areas where your study can be streamlined for efficiency, cost savings, and participant-experience.
4. Recommend – I provide clear, actionable suggestions you can use to improve your protocol.

How to Start

Ready to begin? Choose the study definition you'd like me to optimize and click enter to get started.

Study space: jill
Study definition: BP30037
Revision: Jan 6, 2026, 9:15 AM PST

Study definition successfully validated. Now optimizing your study definition. This may take some time. You can leave this page and return later when the optimization report is ready.

[Optimization Report](#)

Coming soon: in upcoming updates you'll be able to use this chat to ask questions about and make modifications to

Optimization Report Download

Clinical Trial Optimization Report

TUFTS CSDD Framework Analysis

BP30037 Phase II Trial • 70 Participants • 57 Activities Analyzed

Executive Summary

Study Overview

Cost and Operational Classification Analysis

Optimization Recommendations

Projected Total Impact

Conclusions

Appendices

Appendix A: All Recommendations

Appendix B: Methodology

References

Executive Summary

Total Cost Savings **\$1,002,330** ↓ 37%

| | |
|--------|-------------|
| Before | \$2,736,440 |
| After | \$1,734,110 |

The optimization process for this Phase 2A study in primary Sjögren's syndrome identified opportunities to reduce participant burden and operational complexity while preserving all critical efficacy and safety assessments. Through careful analysis of 54 study activities, we implemented targeted reductions in non-essential procedures, eliminated redundant assessments, and streamlined data collection methods. The optimization strategy maintained the integrity of the primary endpoint (ESSDAI at Week 12) and all secondary endpoints while achieving meaningful reductions in blood volume (32% decrease from 250.3 mL to 170.8 mL per participant) and overall participant time burden (9% reduction). Key optimizations included consolidating duplicate baseline assessments, reducing frequency of exploratory biomarkers to baseline and end-of-treatment only, and implementing electronic data capture methods for patient-reported outcomes and routine safety assessments.

Participant Impact

| | | |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <p>\$14,319 ↓ 37%</p> <p>Cost Savings per Participant</p> <p>Before \$39,092 After \$24,773</p> | <p>1h 35m ↓ 9%</p> <p>Participant Time Savings</p> <p>Before 17h 39m After 16h 4m</p> | <p>79.5 mL ↓ 32%</p> <p>Blood Volume Reduction per Participant</p> <p>Before 250.3 mL After 170.8 mL</p> |
| <p>2h 35m ↓ 13%</p> <p>Study Coordinator Time Savings per Participant</p> <p>Before 19h 39m After 17h 4m</p> | <p>20m ↓ 5%</p> <p>Principal Investigator Time Savings per Participant</p> <p>Before 6h 15m After 5h 55m</p> | <p>7.10 RVU ↓ 14%</p> <p>Complexity Reduction per Participant</p> <p>Before 49.70 RVU After 42.60 RVU</p> |

Site Impact

Key Findings

- Blood volume burden reduced by 79.5 mL per participant (32% reduction) through elimination of redundant and non-essential laboratory assessments
- Total participant time reduced by 95 minutes (9% decrease) while maintaining all scheduled visits and core assessments
- Electronic data capture implementation for PROs and safety assessments improved data quality without increasing participant burden
- All Core activities supporting primary and secondary endpoints were preserved at their original frequency
- Exploratory biomarker collections were streamlined to baseline and end-of-treatment timepoints, maintaining scientific value while reducing operational complexity
- Optional salivary gland biopsy approach reduced invasive procedures while preserving exploratory tissue analysis capability

🔍 The optimization strategy protects two critical categories: Core activities that measure primary and key secondary endpoints, and Required Activities mandated by regulations. Cost savings come exclusively from non-Core activities that collect exploratory or supplemental data. Detailed optimization strategies for each activity are available in the appendices.

Study Overview

ICH-M11Templatedemo 16 Search for tools, help, and more (Option + Q) MC

File Home Insert Layout References Review View Help Table Faro (demo) Comments Catch up Editing Share

Authoring

Full Title:
Trial Phase:
Short Title:
Regulatory or Clinical Trial Identifier(s):

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| 1.2 TRIAL SCHEMA | 1 |
| 1.3 SCHEDULE OF ACTIVITIES | 1 |
| 2 INTRODUCTION | 1 |
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Faro Authoring (demo) ... ✕

Sections Schedule ...

- 1 PROTOCOL SUMMARY
 - 1.1 Protocol Synopsis
 - 1.2 Trial Schema
 - 1.3 Schedule of Activities
- 2 INTRODUCTION
 - 2.1 Purpose of Trial
 - 2.2 Assessment of Risks and Benefits
 - 2.2.1 Risk Summary and Mitigation Strategy
 - 2.2.2 Benefit Summary
 - 2.2.3 Overall Risk-Benefit Assessment
- 3 TRIAL OBJECTIVES AND ASSOCIATED ESTIMANDS
 - 3.1 Primary Objective(s) and Associated Estimand(s)

EX611816-01 Solid Tumor (v2) MC

Faro
EX611816-01 Solid Tumor (v2)

Study Spaces

- Protocol Import
- Protocol Optimization

EX611816 - CDISC Webinar Versior

Study Framework

- Overall Design Summary
- Study Interventions
- Activity Configuration
- Statistical Considerations

Study Definition

- EX611816-01 Solid Tumor...
- Objectives and Endpoi...
- Population Summary
- Inclusion Criteria
- Exclusion Criteria
- Study Design
- Import

Data

- Insights
- Compare

Chat with us

MC Maxine Chan

General Information

Study Definition

Version **29 June 2022**

Participating Countries **Empty**

Study

Protocol Number **EX-611816**

Program **Empty**

Type **Interventional**

Primary Disease Area **Solid Tumors X**

Other Disease Areas **Empty**

Primary Therapeutic Area **Oncology X**

Phase **Phase Ib Trial X Phase II Trial X**

Protocol Title **A Phase 1b/2 Open-Label Study of the Efficacy and Safety of Etigilimab (MPH313) Administered in Combination with Nivolumab to Subjects with Locally Advanced or Metastatic Solid Tumors (ACTIVATE)**

Protocol Title (Short) **Empty**

Acronym **Empty**

Registry Identifier Number **NCT123456789**

Sponsor **Example Therapeutics**

Vendors

Contract Research Organization **Empty**

Central Lab **Empty**

Electronic Data Capture **Veeva EDC**

Study was successfully pushed to Veeva EDC by Maxine Chan at Feb 6, 2026, 2:18 PM. [View study](#)

Additional Information

EDC Study Name **EX611816-01**

EDC Organization **Faro**

STUDY DESIGN

Schedule

Study Settings

Assessments (0)

Email Groups (0)

Form Links (0)

Review Plans (0)

Integration Config (0)

STUDY OBJECTS

Codelists (0)

Event Groups (7)

Events (11)

Forms (34)

Item Groups (1)

Items (1)

Units (0)

Subject Groups (0)

RULES

Casebook Variables (0)

Comparison Rules (0)

Schedule Use drag and drop editor

[Edit Relationships](#) + New Event Group

Search Forms + New Form

| Name | Label | Screening Day -1 | Cycle 1 Day 1 | Cycle 1 Day 3 | Cycle 1 Day 8 | Cycle 2 Day 21 | Cycle 2 Day 28 | Cycle 3 Day 35 | Cycle 3 Day 42 | Cycle 4 Day 48 | Cycle 5 Day 70 | Cycle 6 And Beyond D... |
|-----------------------------|-----------------------------|--------------------|-----------------|-----------------|-----------------|------------------|------------------|------------------|------------------|------------------|------------------|---------------------------|
| 12_lead_ecg | 12 Lead ECG | ✓ | ✓ | | | | | | ✓ | | | |
| adverse_events | Adverse Events | | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | |
| antidrug_antibody_testin... | antidrug_antibody_testin... | | ✓ | | ✓ | | ✓ | | | ✓ | | |
| aptt_by_coagulation_as... | APTT by Coagulation As... | ✓ | | | | | | | | | | |
| archived_sample_ffpe | Archived Sample FFPE | ✓ | | | | | | | | | | |
| body_height | Body Height | ✓ | | | | | | | | | | |
| body_weight | Body Weight | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | |
| circulating_free_dna_cfd... | circulating_free_dna_cfd... | ✓ | ✓ | | | | | ✓ | | | | ✓ |
| coagulation_panel_pt_p... | coagulation_panel_pt_p... | ✓ | | | | | | | | | | |
| comprehensive_physica... | Comprehensive Physica... | ✓ | | | | | | | | | | |
| concomitant_medications | Concomitant Medications | | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | |
| ct_scan_head_w_contrast | ct_scan_head_w_contrast | ✓ | | | | | | | | | | |