

FIAS REGISTRY OF RESEARCH SPECIFICATIONS

ARRIVE 2.0 Essential-10 Planning Profile for Small Murine Immunology Pilot Studies

REGISTRY IDENTIFIER

FOAR-CON2X-Z5JK5D7ST

OBJECT TYPE

Profile of an external standard

DOCUMENT MATURITY

Stable

PUBLISHED

01 July 2021, 12:00 UTC

AUTHORITATIVE VERSION

Registration records the outcome of the Registry review for this version: the submission was sufficiently identified, documented, and internally determinate for the stated procedure. Scope, adoption, and competing conventions are documented separately where relevant.

VERSION

1.0

SUBJECT AREA

Other

SUBMITTED

22 March 2021, 12:00 UTC

LICENCE

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REGISTRY STATUS

Registered

01 July 2021, 12:00 UTC

Core description

SUBMISSION KIND

New registry concept

FULL TITLE

ARRIVE 2.0 Essential-10 Planning Profile for Small Murine Immunology Pilot Studies

SHORT TITLE OR ACRONYM

A2E10-MIP

OBJECT TYPE

Profile of an external standard

STATUS CLAIMED BY THE SUBMITTER

Profile of an external standard

MATURITY OF THIS VERSION

Stable

VERSION

1.0

PRINCIPAL SUBJECT AREA

Other

KEYWORDS

- biomedical research
- mouse study
- immunology
- ARRIVE 2.0
- reporting checklist
- reproducibility

PROBLEM, SCOPE, AND EXCLUSIONS

This profile converts the ARRIVE 2.0 Essential 10 into a planning-and-release gate for small exploratory mouse immunology studies. It requires a structured answer for each essential item before a manuscript or internal report is released. Its scope is limited to planning and release documentation for animal studies; ethical authorization, biological validity, intervention design, clinical research, and full Recommended Set conformance remain outside the profile.

INTENDED USERS AND CONTEXTS

- Preclinical immunology project teams using mouse models
- Animal-facility and methods staff reviewing study records
- Data stewards preparing a reproducibility package for publication

RELATION TO EXISTING PRACTICE

Profiles an existing standard

SCIENTIFIC CONTEXT, SOURCES, AND SCHOLARLY DISCUSSION

This section describes the scientific background, underlying work, and sources of the specification, together with the research groups and scholarly settings in which the proposed solution or its formalisation was presented or discussed. It documents the context and nature of these scholarly exchanges.

Transparent reporting of exploratory animal studies depends on decisions made before the experiment as well as on the information retained for publication. N. Percie du Sert et al. (2020) organise ARRIVE 2.0 around the Essential 10, accompanied by a Recommended Set and an explanation of the individual items. This framework provides a shared basis for documenting study design, experimental units, sample size, allocation, blinding, outcomes and analysis.

The ARRIVE 2.0 revision was developed through an international working group and a Delphi consultation, with support from the NC3Rs. Its practical use, including the Essential 10, was presented to the research community in the NC3Rs webinar delivered by N. Percie du Sert on 18 August 2020. This provides a documented setting for the communication of the reporting requirements underlying the planning profile.

Small murine immunology studies in biomedical research environments such as Institut Cochin face the practical task of applying them to exploratory work with limited resources and evolving hypotheses. Using the requirements during planning helps make decisions explicit before results are available and preserves their rationale for later examination.

The profile translates the Essential 10 into a structured planning and release procedure. Each item receives a documented response, and a reproducible check establishes whether the report contains the required information before release. This creates continuity between the planned study, the experimental record and the material available to readers and reviewers. The specification gives research groups a common documentary framework for examining the completeness of small pilot studies.

References:

- Percie du Sert, N. et al. (2020), The ARRIVE guidelines 2.0: Updated guidelines for reporting animal research, PLOS Biology 18: e3000410. DOI: <https://doi.org/10.1371/journal.pbio.3000410>
- Percie du Sert, N. et al. (2020), Reporting animal research: Explanation and elaboration for

the ARRIVE guidelines 2.0, PLOS Biology 18: e3000411. DOI: <https://doi.org/10.1371/journal.pbio.3000411>

- NC3Rs. ARRIVE 2.0 webinar, presented by N. Percie du Sert, 18 August 2020. Webinar: <https://arriveguidelines.org/resources/webinar>

- Institut Cochin, centre de recherche biomédicale Inserm-CNRS-Université Paris Cité.
Source: <https://institutcochin.fr/>

EXTERNAL STANDARDISATION STATUS

None intended

LICENCE FOR THE SUBMITTED SPECIFICATION

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PUBLICATION DECLARATION

Yes

Profile of an external standard

BASE STANDARD, VERSION, AND STABLE REFERENCE

ARRIVE Guidelines 2.0, published July 2020 in PLOS Biology: Percie du Sert et al., DOI 10.1371/journal.pbio.3000410, with the companion explanation, DOI 10.1371/journal.pbio.3000411. The base contains an Essential 10 and a separate Recommended Set.

WHAT IS THE CONFORMANCE TARGET?

Document or publication

REQUIRED FEATURES SELECTED FROM THE BASE STANDARD

- Study design, including groups and experimental unit
- Sample size and explanation of how it was decided
- Inclusion and exclusion criteria, including exclusions during analysis
- Randomisation method or a reason it was not used
- Blinding at allocation, conduct, outcome assessment and analysis, as applicable
- Explicitly defined outcome measures and primary outcome for hypothesis testing
- Statistical methods and checks of assumptions
- Experimental animals, including species, strain, sex, age or developmental stage and relevant provenance
- Experimental procedures with what, how, where, when and why
- Results with summary/descriptive statistics and effect estimate with precision where applicable

EXCLUDED OR FORBIDDEN FEATURES

- Full conformance to the ARRIVE Recommended Set remains outside this profile
- Institutional ethical review and French legal requirements remain separate obligations
- Choice of biological model, intervention and statistical software remains project-specific
- Clinical-study, human-participant and diagnostic reporting rules are outside this profile

EXTENSIONS OR LOCAL CONSTRAINTS

Each Essential-10 item receives one of complete, incomplete, not-applicable with justification, or not-yet-known. The planning record additionally stores an immutable protocol timestamp, links to randomisation code where used, identifiers for raw-data packages, and a change note when the final report differs from the preregistered plan. They are recorded as local workflow constraints alongside ARRIVE.

COMPATIBILITY WITH CONFORMING BASE-STANDARD IMPLEMENTATIONS

Compatibility is partial or conditional

COMPATIBILITY EXPLANATION

A conforming record documents every Essential-10 item, but the base ARRIVE 2.0 framework also contains a Recommended Set. The profile therefore supports minimum assessment and planning as a partial ARRIVE 2.0 reporting profile. It preserves the base item meanings and numbering.

PROFILE CONFORMANCE TEST

A second reviewer maps each structured answer to one Essential-10 item and verifies that none is absent. Not-applicable requires a reason specific to the study. Any incomplete or not-yet-known item keeps the record in draft status until completed. The test covers documentary completeness and internal links; scientific results and ethical authorization are evaluated through their own procedures.

Registry review record

Submission received

22 March 2021, 12:00 UTC

Submission received.

Registered

01 July 2021, 12:00 UTC

The profile is registered as a narrow documentary workflow. It preserves the ARRIVE 2.0 Essential-10 meanings, makes its partial relationship to the Recommended Set explicit, and supplies a reproducible release test. Animal-experiment authorization remains with the relevant ethics and legal procedures.