

¹ FELIS: web application for integrated analysis of Japan's national clinicogenomic database (C-CAT)

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⁶ Summary

⁷ Japan's national cancer genomic medicine program aggregates comprehensive genomic profiling (CGP) results and linked clinical information at the Center for Cancer Genomics and Advanced Therapeutics (C-CAT) ([Kohno et al., 2022](#)). These data create unique opportunities for ¹⁰ large-scale, real-world clinicogenomic studies; however, their effective use depends on clinically meaningful questions formulated by domain experts, while the need to design and implement ¹¹ bespoke analytical pipelines remains a substantial barrier to analysis.

¹² FELIS is an open-source, locally deployable web application (R/Shiny) designed for no-code ¹³ interactive analysis of secondary-use C-CAT datasets. It provides a point-and-click interface ¹⁴ for cohort construction, clinicogenomic summarization, visualization, and bias-aware outcome ¹⁵ analyses. By lowering technical barriers while remaining compatible with secured/offline ¹⁶ environments, FELIS helps clinicians and translational researchers iterate rapidly from a clinical ¹⁷ question to a reproducible analysis output.

¹⁸ Several analytical components implemented in FELIS are based on methods previously described ¹⁹ in peer-reviewed publications, including variant-based clustering analysis and survival modeling ²⁰ accounting for delayed entry and left truncation. The scientific contribution of FELIS lies in ²¹ the robust software implementation, integration, and practical accessibility of these methods ²² rather than the introduction of new statistical methodology.

²⁴ Statement of need

²⁵ Large clinicogenomic resources have accelerated discovery by enabling standardized exploration ²⁶ of molecular and clinical features (e.g., cBioPortal ([Cerami et al., 2012](#); [Gao et al., 2013](#)) ²⁷ and AACR Project GENIE ([The AACR Project GENIE Consortium, 2017](#))). However, C- ²⁸ CAT secondary-use data are typically analyzed in controlled environments under data use ²⁹ agreements, limiting the utility of hosted public portals. Moreover, clinically relevant real-world ³⁰ evidence (RWE) questions in CGP practice often require analysis features that are uncommon ³¹ in general-purpose genomics portals—for example, survival modeling that accounts for delayed ³² testing and left truncation, which can meaningfully bias CGP-based outcome analyses ([Ikegami, ³³ 2023; Tamura et al., 2023](#)). FELIS addresses these gaps by offering:

- ³⁴ ▪ **No-code cohort building** from de-identified, preprocessed tables derived from secondary-
use C-CAT datasets.
- ³⁵ ▪ **Bias-aware survival analysis** suitable for CGP settings with delayed entry/left truncation.
- ³⁶ ▪ **Clinically oriented outputs** (tables and figures) designed for downstream reporting and
manuscript preparation.
- ³⁷ ▪ **Privacy-preserving deployment** on a local workstation or institutional server (including
offline/containerized setups), so sensitive data remain within the user's controlled

41 environment.

42 Software description

43 Architecture and deployment

44 FELIS is distributed as an R package that launches an interactive Shiny application. It supports
45 (i) direct installation from source and (ii) container-based deployment to promote reproducibility
46 across heterogeneous computing environments. The application is designed to be usable in
47 restricted networks commonly required for secondary-use clinical data.

48 Data inputs and governance-aware design

49 FELIS operates on research-use datasets prepared from C-CAT secondary-use programs. Users
50 load standardized, de-identified tables (e.g., patient-level clinical variables, tumor metadata,
51 treatments, and variant-level calls) generated by local preprocessing within their authorized
52 environment. This design keeps FELIS open source while accommodating access control and
53 governance constraints of national clinicogenomic data.

54 Core functionality

55 FELIS provides interactive modules that cover common clinicogenomic workflows:

- 56 ▪ **Cohort definition and stratification:** filter and intersect clinical variables (e.g., age, sex,
57 tumor type, stage, lines of therapy) and genomic alterations (genes, variant classes,
58 panels).
- 59 ▪ **Genomic summaries and visualization:** alteration frequency summaries, oncoprint-style
60 views, co-alteration exploration, and subgroup comparisons.
- 61 ▪ **Outcome analysis:** Kaplan–Meier and regression-based survival analyses with options to
62 handle delayed entry/left truncation in CGP settings.
- 63 ▪ **Treatment pattern summarization:** descriptive analyses of real-world treatment sequences
64 and therapy exposure among genetically defined subgroups.
- 65 ▪ **Export for reporting:** download-ready plots and tables to facilitate communication with
66 multidisciplinary teams and manuscript preparation.

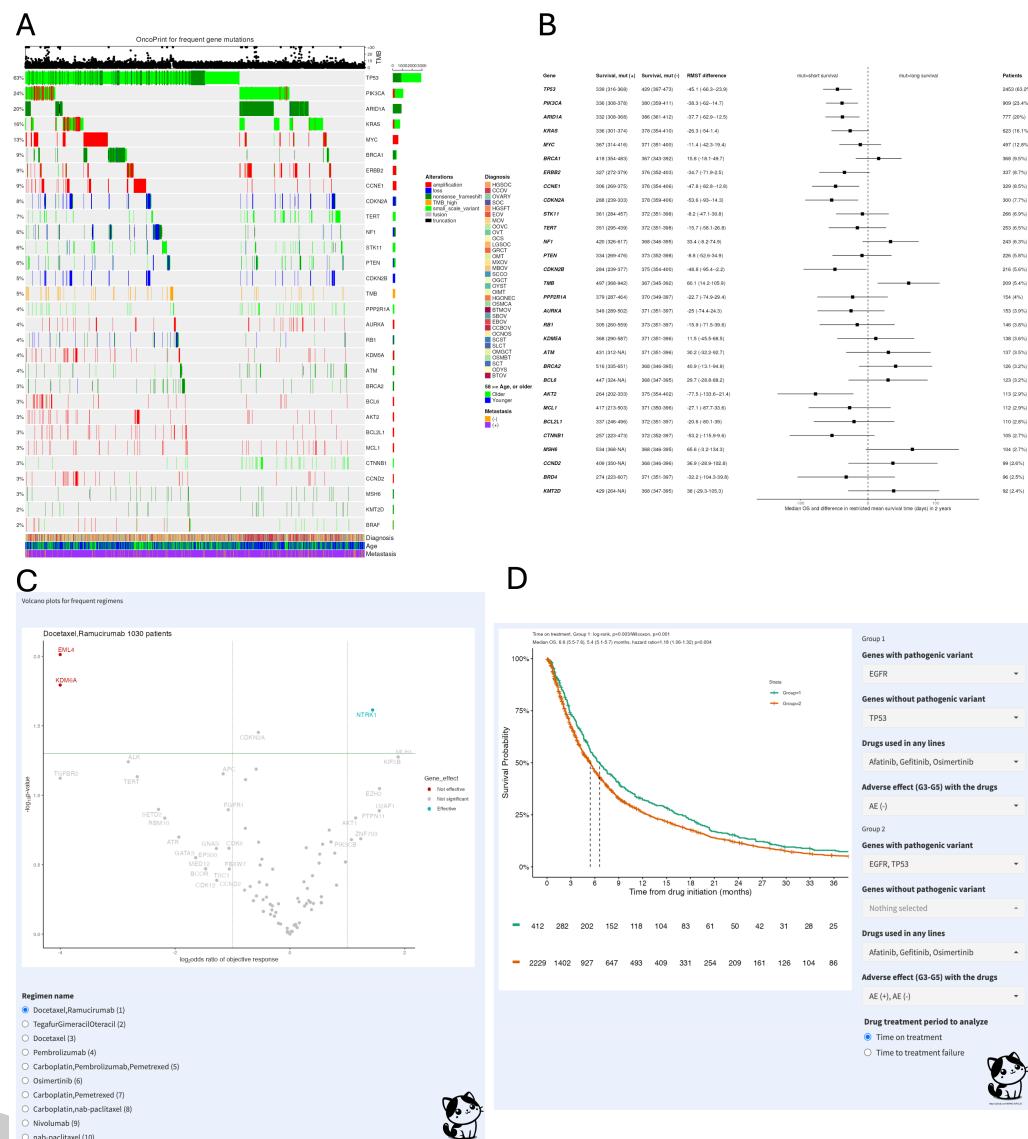


Figure 1: Representative analyses performed using FELIS. (A) OncoPrint summarizing frequently mutated genes across the selected cohort. (B) Forest plot showing the estimated effects of gene alterations on survival outcomes. (C) Volcano plot illustrating gene-level associations with drug response, highlighting effect sizes and statistical significance. (D) Kaplan–Meier survival curves comparing two groups stratified by a user-defined factor within the FELIS interface.

Some of the analytical methods implemented in FELIS have been previously reported in the literature. In particular, the variant-based clustering analysis follows the approach described by Mochizuki(Mochizuki et al., 2024), and the bias-aware survival analysis with correction for delayed entry and left truncation is based on Tamura(Tamura et al., 2023). FELIS provides a unified and reproducible software implementation of these methods tailored to the data structure and governance constraints of Japan’s national clinicogenomic database (C-CAT).

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