Package: r4subprofile (via r-universe)

May 15, 2026

Title Regulatory Submission Profiles for Clinical Submission Readiness

Version 0.1.1

Description Defines submission profiles per regulatory authority with authority-specific pillar weights, decision thresholds, indicator requirements, and risk configuration. Supports the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Therapeutic Goods Administration (TGA), and Medicines and Healthcare products Regulatory Agency (MHRA). Integrates with 'r4subscore' and 'r4subrisk' configuration systems.

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URL `https://r4sub.github.io/r4subprofile/`, `https://github.com/R4SUB/r4subprofile`

BugReports `https://github.com/R4SUB/r4subprofile/issues`

Depends R (>= 4.2)

Imports cli, r4subcore, rlang, tibble

Suggests knitr, r4subscore, r4subrisk, rmarkdown, testthat (>= 3.0.0)

VignetteBuilder knitr

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Contents

`list_authorities` *List Supported Regulatory Authorities*

Description

Returns a summary of all supported regulatory authorities with their full names, countries, and number of available submission types.

Usage

```
list_authorities()
```

Value

A tibble with columns: `authority`, `full_name`, `country`, `n_submission_types`.

Examples

```
list_authorities()
```

`list_submission_types` *List Submission Types for an Authority*

Description

Returns the valid submission types for a given regulatory authority.

Usage

```
list_submission_types(authority)
```

Arguments

`authority`	Character. A supported authority name.

Value

A character vector of valid submission types.

Examples

```
list_submission_types("FDA")
list_submission_types("EMA")
```

`print.profile_validation` *Print Profile Validation Result*

Description

Print Profile Validation Result

Usage

```
## S3 method for class 'profile_validation'
print(x, ...)
```

Arguments

`x`	A `profile_validation` object.
`...`	Ignored.

Value

Invisibly returns `x`. Called for its side effect of printing the compliance status, coverage percentage, and any missing indicators or asset types to the console.

`print.submission_profile` *Print Submission Profile*

Description

Print Submission Profile

Usage

```
## S3 method for class 'submission_profile'
print(x, ...)
```

Arguments

`x`	A `submission_profile` object.
`...`	Ignored.

Value

Invisibly returns `x`. Called for its side effect of printing a summary of the submission profile (authority, submission type, pillar weights, ready band, required indicators, and minimum coverage) to the console.

`profile_required_indicators` *Get Required Indicators for a Profile*

Description

Returns the list of indicator IDs that are mandatory for the given submission profile.

Usage

```
profile_required_indicators(profile)
```

Arguments

`profile`	A `submission_profile` object.

Value

A character vector of required `indicator_id` values.

Examples

```
prof <- submission_profile("FDA", "NDA")
profile_required_indicators(prof)

prof_ind <- submission_profile("FDA", "IND")
profile_required_indicators(prof_ind)
```

`profile_risk_config` *Extract Risk Configuration from a Profile*

Description

Returns a list with structure compatible with `r4subrisk::risk_config_default()`. Can be passed directly to risk assessment functions.

Usage

```
profile_risk_config(profile)
```

Arguments

`profile`	A `submission_profile` object.

Value

A list of class "`risk_config`" with `rpn_bands`, `evidence_severity_to_probability`, `evidence_severity_to_impact`, and `default_detectability`.

Examples

```
prof <- submission_profile("FDA", "NDA")
cfg <- profile_risk_config(prof)
cfg$rpn_bands
```

`profile_sci_config` *Extract SCI Configuration from a Profile*

Description

Returns a list with structure compatible with `r4subscore::sci_config_default()`. Can be passed directly to `compute_pillar_scores()` or `compute_sci()`.

Usage

```
profile_sci_config(profile)
```

Arguments

`profile`	A `submission_profile` object.

Value

A list of class `"sci_config"` with `pillar_weights` and `bands`.

Examples

```
prof <- submission_profile("FDA", "NDA")
cfg <- profile_sci_config(prof)
cfg$pillar_weights
cfg$bands
```

`profile_summary` *Summarize a Submission Profile*

Description

Prints a formatted summary of a regulatory submission profile including authority details, pillar weights, decision bands, and requirements.

Usage

```
profile_summary(profile)
```

Arguments

`profile`	A `submission_profile` object.

Value

The profile object, invisibly.

Examples

```
prof <- submission_profile("FDA", "NDA")
profile_summary(prof)
```

`submission_profile` *Create a Submission Profile*

Description

Constructs a regulatory submission profile with authority-specific pillar weights, decision bands, required indicators, and risk configuration.

Usage

```
submission_profile(authority, submission_type, study_phase = NULL)
```

Arguments

`authority`	Character. Regulatory authority name (e.g., `"FDA"`, `"EMA"`). See `list_authorities()` for all supported values.
`submission_type`	Character. Submission type for the authority (e.g., `"NDA"`, `"MAA"`). See `list_submission_types()` for valid values.
`study_phase`	Character or `NULL`. Optional study phase (e.g., `"Phase1"`, `"Phase2"`, `"Phase3"`, `"Phase4"`). Currently informational.

Value

A list of class `"submission_profile"` with elements: `authority`, `full_name`, `country`, `submission_type`, `study_phase`, `pillar_weights`, `bands`, `required_indicators`, `required_asset_types`, `minimum_coverage`, `rpn_bands`, `default_detectability`.

Examples

```
prof <- submission_profile("FDA", "NDA")
prof$pillar_weights
prof$required_indicators

prof_ema <- submission_profile("EMA", "MAA", study_phase = "Phase3")
prof_ema$bands
```

`validate_against_profile` *Validate Evidence Against a Submission Profile*

Description

Checks whether an evidence table meets the requirements specified by a regulatory submission profile: required indicators present, required asset types covered, and minimum indicator coverage met.

Usage

```
validate_against_profile(evidence, profile)
```

Arguments

`evidence`	A validated evidence data.frame conforming to the r4subcore evidence schema.
`profile`	A `submission_profile` object.

Value

A list of class `"profile_validation"` with elements:

- `is_compliant`: logical; `TRUE` if all requirements are met
- `missing_indicators`: character vector of missing required indicator IDs
- `missing_asset_types`: character vector of missing required asset types
- `coverage`: numeric; fraction of required indicators present (0-1)
- `coverage_met`: logical; whether coverage meets the minimum threshold
- `details`: tibble with per-requirement status

Examples

```
## Not run:
prof <- submission_profile("FDA", "NDA")
result <- validate_against_profile(evidence, prof)
result$is_compliant
result$missing_indicators

## End(Not run)
```

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