

Package ‘r4subprofile’

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Title Regulatory Submission Profiles for Clinical Submission Readiness

Version 0.1.0

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://github.com/R4SUB/r4subprofile>

BugReports <https://github.com/R4SUB/r4subprofile/issues>

Depends R (>= 4.2)

Imports cli, r4subcore, rlang, tibble

Suggests r4subscore, r4subrisk, testthat (>= 3.0.0)

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list_authorities	<i>List Supported Regulatory Authorities</i>
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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	<i>List Submission Types for an Authority</i>
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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

```
ctx <- r4subcore::r4sub_run_context(study_id = "STUDY01")
ev <- r4subcore::as_evidence(
  data.frame(
    asset_type = "dataset", asset_id = "ADSL",
    source_name = "test", source_version = "1.0",
    indicator_id = "Q-001", indicator_name = "Test",
    indicator_domain = "quality", severity = "high",
    result = "fail", metric_value = 1, metric_unit = "n",
    message = "Example finding", location = "ADSL",
    evidence_payload = "{}", stringsAsFactors = FALSE
  ), ctx = ctx
)
prof <- submission_profile("FDA", "NDA")
result <- validate_against_profile(ev, prof)
result$is_compliant
result$missing_indicators
```

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