

Package ‘spiritR’

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Title Template for Clinical Trial Protocol

Version 0.1.1

Description Contains an R Markdown template for a clinical trial protocol adhering to the SPIRIT statement. The SPIRIT (Standard Protocol Items for Interventional Trials) statement outlines recommendations for a minimum set of elements to be addressed in a clinical trial protocol. Also contains functions to create a xml document from the template and upload it to clinicaltrials.gov<<https://www.clinicaltrials.gov/>> for trial registration.

URL <https://github.com/awconway/spiritR>

BugReports <https://github.com/awconway/spiritR/issues>

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Encoding UTF-8

LazyData true

Imports xml2, httr, magrittr

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Suggests testthat, knitr, rmarkdown, pkgdown, covr

VignetteBuilder knitr

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NeedsCompilation no

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add_functions	<i>Add arms, interventions and outcomes to an existing xml document for upload to clinicaltrials.gov</i>
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Description

These functions add arms, interventions, primary and secondary outcomes as well as conditions and keywords to an xml document created using the create_ctxml() function. Calls to these functions should not be assigned to an object.

Usage

```
add_arm(ctxml, arm_label, arm_type, arm_desc)
```

```
add_intervention(ctxml, int_name, int_type, int_desc, arm_label)
```

```
add_pr_outcome(ctxml, name, time, description)
```

```
add_sec_outcome(ctxml, name, time, description)
```

```
add_condition(ctxml, condition)
```

```
add_keyword(ctxml, keyword)
```

Arguments

ctxml	A xml document generated from the create_ctxml() function
arm_label	Label assigned to arm of clinical trial. Arm means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention).
arm_type	Either Experimental, Active comparator, Placebo Comparator, Sham Comparator, No Intervention, or Other.
arm_desc	Description of the arm.
int_name	Name of the intervention. For a drug, it is the generic name.
int_type	Drug, Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioural, Genetic, Dietary Supplement, Combination Product, Diagnostic Test, or Other.
int_desc	Other details about the intervention not included in name.
name	Name of outcome measure.
time	Time point(s) at which the measurement is assessed.
description	Other details about the outcome measure not included in the name
condition	MeSH term for condition being studied in the trial, or Focus of the Study
keyword	Words or phrases that best describe the protocol. Keywords help users find studies in the database.

Details

- `add_arm()`: Adds an xml nodespace containing information about the arm name, type and description to the xml document.
- `add_intervention()`: Adds an xml nodespace containing information about the intervention name, type, description and arm it is associated with to the xml document.
- `add_pr_outcome()`: Adds an xml nodespace containing information about the outcome name, time frame for measurement and additional descriptive details to the xml document.
- `add_sec_outcome()`: Adds an xml nodespace containing information about the outcome name, time frame for measurement and additional descriptive details to the xml document.
- `add_condition()`: Adds an xml nodespace containing a MeSH term for the condition being studied in the trial, or Focus of the Study to the xml document.
- `add_keyword()`: Adds an xml nodespace containing a Words or phrases that best describe the protocol. Keywords help users find studies in the database to the xml document.

Value

A xml document

Examples

```
args_ctxml <- list(
  org_name = "UHNToronto",
  org_study_id = "Foo trial 20190806",
  brief_title = "Foo trial to test auto upload 20190806",
  study_acronym = "N/A",
  official_title = "Foo trial to test auto upload: A randomized trial new 20190806",
  agency = "Aaron Conway",
  resp_party_type = "Sponsor-Investigator",
  investigator_username = "aconway",
  investigator_title = "Assistant Professor",
  brief_summary = "Lay summary here",
  start_date = "2019-10",
  primary_compl = "2020-12",
  study_compl = "2020-12",
  int_subtype = "Health Services Research",
  phase = "N/A",
  assignment = "Parallel",
  allocation = "Randomized",
  no_masking = "False",
  masked_subject = "True",
  masked_caregiver = "True",
  masked_investigator = "True",
  masked_assessor = "True",
  number_arms = 2,
  sample_size = "40",
  eligibility_criteria = "Inclusion Criteria
- Adults
Exclusion Criteria"
```

```

- Children",
healthy_volunteers = "No",
genders_included = "Both",
gender_based = "No",
min_age = "1 years",
max_age = "N/A",
#Central contact
contact_first_name = "Aaron",
contact_last_name = "Conway",
contact_degrees = "PhD",
contact_phone = "649-728-8499",
contact_email = "aaron.conway@utoronto.ca",
#Overall official
official_first_name = "Aaron",
official_last_name = "Conway",
official_degrees = "PhD",
official_affiliation = "UHN",
official_role = "Study Principal Investigator",
#Sharing statements
ipd_sharing = "Yes",
ipd_description = "details",
ipd_protocol = "True",
ipd_sap = "True",
ipd_icf = "True",
ipd_csr = "True",
ipd_code = "True",
ipd_time = "details",
ipd_criteria = "details",
ipd_url = "http://www.aaronconway.info"
)

ctxml <- do.call(create_ctxml, args_ctxml)

add_arm(ctxml = ctxml,
        arm_label = "Standard",
        arm_type = "Active Comparator",
        arm_desc = "Manual upload to registry")

add_intervention(ctxml = ctxml,
                 int_type = "Device",
                 int_name = "Registry entry",
                 int_desc = "The usual way to enter to the registry",
                 arm_label = "Standard")

add_pr_outcome(ctxml = ctxml,
               name = "correct upload",
               time = "As measured",
               description = "Insert description about the measure.")

add_sec_outcome(ctxml = ctxml,
                name = "time to upload",
                time = "As measured",

```

```

        description = "Insert description about the measure.")

add_condition(ctxml = ctxml,
              condition = "Cardiac")

add_keyword(ctxml = ctxml,
            keyword = "sedation")

```

create_ctxml

Creates xml document for upload to clinicaltrials.gov

Description

This function will create an xml document conforming to clinicaltrials.gov requirements for automatic upload to the registry

Usage

```

create_ctxml(org_name, org_study_id, brief_title, study_acronym,
             official_title, agency, resp_party_type, investigator_username,
             investigator_title, brief_summary, start_date, study_compl,
             primary_compl, int_subtype, phase, assignment, allocation, no_masking,
             masked_subject, masked_caregiver, masked_investigator, masked_assessor,
             number_arms, sample_size, eligibility_criteria, healthy_volunteers,
             genders_included, gender_based, min_age, max_age, official_first_name,
             official_last_name, official_degrees, official_role,
             official_affiliation, contact_first_name, contact_last_name,
             contact_degrees, contact_phone, contact_email, ipd_sharing,
             ipd_description, ipd_protocol, ipd_sap, ipd_icf, ipd_csr, ipd_code,
             ipd_time, ipd_criteria, ipd_url)

```

Arguments

org_name	The code for the organisation name associated with your PRS clinicaltrials.gov log-in details.
org_study_id	Must be a unique study number from the organization. Sometimes it is the number associated with the funding received or submission for institutional approval.
brief_title	Brief title for the study with a limit of 300 characters
study_acronym	limit to 14 characters or enter n/a
official_title	Study title limited to 600 characters
agency	Name of the lead sponsor. This would be the name of the principal investigator if it is a Sponsor-Investigator trial.
resp_party_type	Either: Sponsor; Principal Investigator (responsible party designated by sponsor) or Sponsor-Investigator (individual who initiates and conducts study).

investigator_username	The username associated with your clinicaltrials.gov log-in
investigator_title	Official title e.g. Assistant Professor
brief_summary	A short description of the clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public. Limit is 5000 characters.
start_date	Anticipated start date written in yyyy-mm format
study_compl	The anticipated date (written in yyyy-mm) that the final participant was examined or received an intervention for purposes of final collection of data
primary_compl	Anticipated date written in yyyy-mm-dd format. The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome.
int_subtype	Either: Treatment; Prevention; Diagnostic; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; or Other.
phase	Either: N/A (for trials that do not involve drug or biologic products); Early Phase 1; Phase1/Phase 2; Phase 2; Phase2/Phase 3; Phase 3; or Phase 4.
assignment	Either: Single group; Parallel; Crossover; Factorial; or Sequential.
allocation	Either: Randomized; or Non-randomized.
no_masking	True/False
masked_subject	True/False
masked_caregiver	True/False
masked_investigator	True/False
masked_assessor	True/False
number_arms	Number of arms. "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.
sample_size	Planned sample size
eligibility_criteria	Textbox containing both inclusion and exclusion criteria
healthy_volunteers	Trial is recruiting healthy volunteers for participation. Answer is either: Yes; or No.
genders_included	Either: Female; Male; or Both.
gender_based	If applicable, indicate if eligibility is based on self-representation of gender identity. Answer is either: Yes; or No.
min_age	Numeric with years - e.g. 16 years or 'N/A (No Limit)'
max_age	Numeric with years - e.g. 80 years or 'N/A (No Limit)'

official_first_name	Overall official first name
official_last_name	Overall official last name
official_degrees	Overall official degrees/qualifications
official_role	Either: Study Chair; Study Director or Study Principal Investigator.
official_affiliation	Full name of the official's organization. If none, specify Unaffiliated.
contact_first_name	Central contact first name
contact_last_name	Central contact last name
contact_degrees	Central contact's degrees/qualifications
contact_phone	Central contact phone number
contact_email	Central contact email
ipd_sharing	Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Either: Yes; No; Undecided.
ipd_description	If yes, describe the IPD sharing plan, including what IPD are to be shared with other researchers.
ipd_protocol	Study protocol to be shared: True/False
ipd_sap	Statistical analysis plan to be shared: True/False
ipd_icf	Information consent form to be shared: True/False
ipd_csr	Clinical study report to be shared: True/False
ipd_code	Analytic code to be shared: True/False
ipd_time	A description of when the IPD and any additional supporting information will become available and for how long, including the start and end dates or period of availability. Limit 1000 characters.
ipd_criteria	Describe by what access criteria IPD and any additional supporting information will be shared, including with whom, for what types of analyses, and by what mechanism. Limit 1000 characters.
ipd_url	The web address, if any, used to find additional information about the plan to share IPD.

Value

A xml document

Examples

```

args_ctxml <- list(
  org_name = "UHNToronto",
  org_study_id = "Foo trial 20190806",
  brief_title = "Foo trial to test auto upload 20190806",
  study_acronym = "N/A",
  official_title = "Foo trial to test auto upload: A randomized trial new 20190806",
  agency = "Aaron Conway",
  resp_party_type = "Sponsor-Investigator",
  investigator_username = "aconway",
  investigator_title = "Assistant Professor",
  brief_summary = "Lay summary here",
  start_date = "2019-10",
  primary_compl = "2020-12",
  study_compl = "2020-12",
  int_subtype = "Health Services Research",
  phase = "N/A",
  assignment = "Parallel",
  allocation = "Randomized",
  no_masking = "False",
  masked_subject = "True",
  masked_caregiver = "True",
  masked_investigator = "True",
  masked_assessor = "True",
  number_arms = 2,
  sample_size = "40",
  eligibility_criteria = "Inclusion Criteria
- Adults
Exclusion Criteria
- Children",
  healthy_volunteers = "No",
  genders_included = "Both",
  gender_based = "No",
  min_age = "1 years",
  max_age = "N/A",
  #Central contact
  contact_first_name = "Aaron",
  contact_last_name = "Conway",
  contact_degrees = "PhD",
  contact_phone = "649-728-8499",
  contact_email = "aaron.conway@utoronto.ca",
  #Overall official
  official_first_name = "Aaron",
  official_last_name = "Conway",
  official_degrees = "PhD",
  official_affiliation = "UHN",
  official_role = "Study Principal Investigator",
  #Sharing statements
  ipd_sharing = "Yes",
  ipd_description = "details",
  ipd_protocol = "True",
  ipd_sap = "True",

```



```
ipd_icf = "True",
ipd_csr = "True",
ipd_code = "True",
ipd_time = "details",
ipd_criteria = "details",
ipd_url = "http://www.aaronconway.info"
)

ctxml <- do.call(create_ctxml, args_ctxml)
```

print_ctxml

Print xml document created using spiritR

Description

This function allows you to easily view the structure of the xml document generated using the create_ctxml() function

Usage

```
print_ctxml(ctxml)
```

Arguments

ctxml The xml document generated by a call to create_ctxml()

Examples

```
args_ctxml <- list(
  org_name = "UHNToronto",
  org_study_id = "Foo trial 20190806",
  brief_title = "Foo trial to test auto upload 20190806",
  study_acronym = "N/A",
  official_title = "Foo trial to test auto upload: A randomized trial new 20190806",
  agency = "Aaron Conway",
  resp_party_type = "Sponsor-Investigator",
  investigator_username = "aconway",
  investigator_title = "Assistant Professor",
  brief_summary = "Lay summary here",
  start_date = "2019-10",
  primary_compl = "2020-12",
  study_compl = "2020-12",
  int_subtype = "Health Services Research",
  phase = "N/A",
  assignment = "Parallel",
  allocation = "Randomized",
  no_masking = "False",
  masked_subject = "True",
  masked_caregiver = "True",
```

```

masked_investigator = "True",
masked_assessor = "True",
number_arms = 2,
sample_size = "40",
eligibility_criteria = "Inclusion Criteria
- Adults
Exclusion Criteria
- Children",
healthy_volunteers = "No",
genders_included = "Both",
gender_based = "No",
min_age = "1 years",
max_age = "N/A",
#Central contact
contact_first_name = "Aaron",
contact_last_name = "Conway",
contact_degrees = "PhD",
contact_phone = "649-728-8499",
contact_email = "aaron.conway@utoronto.ca",
#Overall official
official_first_name = "Aaron",
official_last_name = "Conway",
official_degrees = "PhD",
official_affiliation = "UHN",
official_role = "Study Principal Investigator",
#Sharing statements
ipd_sharing = "Yes",
ipd_description = "details",
ipd_protocol = "True",
ipd_sap = "True",
ipd_icf = "True",
ipd_csr = "True",
ipd_code = "True",
ipd_time = "details",
ipd_criteria = "details",
ipd_url = "http://www.aaronconway.info"
)

ctxml <- do.call(create_ctxml, args_ctxml)

print_ctxml(ctxml)

```

upload_ctxml

Upload an xml object to the clinicaltrials.gov registry

Description

This function will make a http POST request to upload a XML document to the clinicaltrials.gov registry.

Usage

```
upload_ctxml(ctxml, org_name, user_name, password)
```

Arguments

<code>ctxml</code>	A xml document created using <code>create_ctxml()</code> and updated with any <code>add_arms()</code> , <code>add_interventions()</code> , <code>add_pr_outcomes()</code> and <code>add_sec_outcomes()</code> that may be required.
<code>org_name</code>	The organisation name associated with a <code>clinicaltrials.gov</code> account
<code>user_name</code>	Username for a <code>clinicaltrials.gov</code> account
<code>password</code>	Password for a <code>clinicaltrials.gov</code> account

Value

A message from a http post request to show that the upload was successful or unsuccessful

Examples

```
## Not run:  
upload_ctxml(ctxml = ctxml, org_name = "UHNToronto", user_name = "aconway",  
  password = "password")  
  
## End(Not run)
```

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