Package ‘spiritR’

October 14, 2022

**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. It also contains functions to create an 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

**License**  MIT + file LICENSE

**Encoding**  UTF-8

**LazyData**  true

**Imports**  xml2, httr, magrittr

**RoxygenNote**  6.1.1

**Suggests**  testthat, knitr, rmarkdown, pkgdown, covr

**VignetteBuilder**  knitr

**Language**  en-US

**NeedsCompilation**  no

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**R topics documented:**

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add_functions

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add_functions Add arms, interventions and outcomes to an existing xml document for upload to clinicaltrials.gov

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

tctxml 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.
add_functions

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

```r
dargs_ctxml <- list(
  org_name = "UHN\nToronto",
  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",
create_ctxml

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)'
create_ctxml

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

```r
args_ctxml <- list(
  org_name = "UHN_Toronto",
  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",
  contact_first_name = "Aaron",
  contact_last_name = "Conway",
  contact_degrees = "PhD",
  contact_phone = "649-728-8499",
  contact_email = "aaron.conway@utoronto.ca",
  official_first_name = "Aaron",
  official_last_name = "Conway",
  official_degrees = "PhD",
  official_affiliation = "UHN",
  official_role = "Study Principal Investigator",
  ipd_sharing = "Yes",
  ipd_description = "details",
  ipd_protocol = "True",
  ipd_sap = "True",
)```
print_ctxml

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 = "UHN/Toronto",
  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"
)

cxml <- do.call(create_ctxml, args_ctxml)

print_ctxml(cxml)

---

**Description**

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

Usage

upload_ctxml(ctxml, org_name, user_name, password)

Arguments

cctxml  A xml document created using create_ctxml() and updated with any add_arms(),
        add_interventions(), add_pr_outcomes() and add_sec_outcomes() that may be
        required.
org_name  The organisation name associated with a clinicaltrials.gov account
user_name  Username for a clinicaltrials.gov account
password  Password for a clinicaltrials.gov 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 ="UHN Toronto", user_name = "aconway",
password = "password")

## End(Not run)
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