

表1 WHO primary/associate registerとして指定を受けるための基本要件20項目とUMIN登録情報との対応

	Item	Field Value	Definition/Explanation	UMIN
1	Primary Register and Trial ID #	Trial ID #	Name of Primary Register, and the unique ID number assigned by the Primary Register to this trial.	UMIN 試験ID
2	Date of Registration in Primary Register		Date when trial was officially registered in the Primary Register YYYY/MM/DD.	管理情報/登録日
3	Secondary ID#s	Issuing Authority ID Number Click to add more ...	Other identifying numbers and issuing authorities besides the Primary Register, if any. Include the sponsor name and sponsor-issued trial number (e.g., protocol number) if available. Also include other trial registers that have issued an ID number to this trial. There is no limit on the number of Secondary ID numbers that can be provided.	試験ID1 ID発行機関1 試験ID2 ID発行機関2 治験届 プロトコル番号は試験名、試験簡
4	Source(s) of Monetary or Material Support	Name Click to add more...	Major source(s) of monetary or material support for the trial (e.g., funding agency, foundation, company).	研究費提供組織 組織の区分 その他の研究費提供組織
5	Primary Sponsor	Name	The individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting). In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main funder.	実施責任組織 研究費提供組織
6	Secondary Sponsor(s)	Name Click to add more...	Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed to take on all the responsibilities of sponsorship jointly with the primary sponsor; or to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or to act as the sponsor's legal representative in relation to some or all of the trial sites; or to take responsibility for the accuracy of trial registration information submitted.	共同実施組織 その他の研究費提供組織
7	Contact for Public Queries	Email, telephone number, or address	Email address, telephone number, or postal address of the contact who will respond to general queries, including information about current recruitment status	試験問い合わせ窓口/ E-mail 電話 住所
8	Contact for Scientific Queries	Email, telephone number, or address Affiliation	Email address, telephone number, or postal address, and affiliation of the person to contact for scientific queries about the trial (e.g., principal investigator, medical director employed by the sponsor). For a multi-center study, enter the contact information for the lead Principal Investigator or overall scientific director.	E-mailとTelはない。 責任研究者/ 住所 所属組織 所属部署

	Item	Field Value	Definition/Explanation	UMIN
9	Public Title		Title intended for the lay public in easily understood language.	試験簡略名
10	Scientific Title	Acronym	Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available.	試験名
11	Countries of Recruitment		The countries from which participants will be, are intended to be, or have been recruited.	ない
12	Health Condition(s) or Problem(s) Studied		Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g., preventative or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.	対象疾患名 健常人を対象の場合、健常人が意図した対象であれば(e.g. 予防ならば予防の対象疾患)それを、予備的な安全性試験のように、意図した対象でなければユーザーがわかりやすいキーワードを決める。
13	Intervention(s)	Intervention name(s) Other details (e.g., dose, duration, etc.) Click to add more experimental interventions... Control Intervention name Other details	Enter the specific name of the intervention(s) and the comparator/control(s) being studied. Use the International Non-Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g., "low-fat diet, exercise"). The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that intervention, or enter "placebo" or "no treatment" as applicable. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc.)	介入1 介入2 介入3 コントロール
14	Key Inclusion and Exclusion Criteria	Inclusion Criteria Exclusion Criteria	Inclusion and exclusion criteria for participant selection, including age and sex.	年齢(下限)、 年齢(上限) 性別 選択基準、除外基準
15	Study Type		A single arm study is one in which all participants are given the same intervention. Trials in which participants are assigned to receive one of two or more interventions are NOT single arm studies. Crossover trials are NOT single arm studies. A trial is "randomized" if participants are assigned to intervention groups using a method based on chance.	群数 ランダム化
16	Date of First Enrollment		Anticipated or actual date of enrollment of the first participant (YYYY/MM).	登録・組入れ開始(予定)日
17	Target Sample Size		Number of participants that this trial plans to enroll.	目標参加者数