- **Description** - Additional information about the outcome measure, if needed for clarification. (Limit: 999 characters)
- **Safety Issue?** (FDAAA) - Is this outcome measure assessing a safety issue? Select: Yes/No

Examples:

Title: all cause mortality
Time Frame: one year
Safety Issue: No

Title: Evidence of clinically definite ischemic stroke (focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI
Time Frame: within the first 30 days (plus or minus 3 days) after surgery
Safety Issue: Yes

Secondary Outcome Measures FDAAA
Definition: Secondary measurements that will be used to evaluate the intervention (s) or, for observational studies, that are a focus of the study. Specify Title, Time Frame, Description (if needed) and Safety Issue as described above.

Other Pre-specified Outcome Measures
Definition: Any other measurements, excluding post-hoc measures, that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. Specify Title, Time Frame, Description (if needed) and Safety Issue.

▼ 10. Eligibility

Gender * FDAAA
Definition: Physical gender of individuals who may participate in the protocol. Select one.

- Both: both female and male participants are being studied
- Female: only female participants are being studied
- Male: only male participants are being studied

Age Limits * FDAAA

Minimum Age
Definition: Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.

Maximum Age
Definition: Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.

Accepts Healthy Volunteers? FDAAA
Definition: Indicate if persons who have not had the condition(s) being studied or

otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.

Eligibility Criteria * **FDAAA**

Definition: Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria as shown below. (Limit: 15,000 characters)

Example:

```
Inclusion Criteria:
     - Clinical diagnosis of Alzheimer's Disease
     - Must be able to swallow tablets

Exclusion Criteria:
     - Insulin dependent diabetes
     - Thyroid disease
```

Study Population Description *

Definition: For observational studies only, a description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town). (Limit: 1000 characters)

Sampling Method * - For observational studies only, select one and explain in Detailed Description.

- Probability Sample: exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive patient sampling
- Non-Probability Sample: any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer

▼ 11. Contacts, Locations, and Investigator Information

Multiple locations may be specified. Location is composed of the following fields.

Central Contact * **(FDAAA)** (or Facility Contact required)

Definition: Person providing centralized, coordinated recruitment information for the entire study.

- First Name
- Middle Initial
- Last Name * **(FDAAA)**
- Degree
- Phone * **(FDAAA)**: Toll free phone number of the central contact. person. Use the format 800-555-5555 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email * **(FDAAA)**: electronic mail address of the central contact person

Central Contact Backup
Person to contact if Central Contact is not available.

Overall Study Officials
Definition: Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator.

- First Name
- Middle Initial
- Last Name
- Degree
- Organizational Affiliation: Full name of the official's organization. If none, specify Unaffiliated.
  (Limit: 255 characters)
- Official's Role: Position or function of the official. Select one (Study Chair/Study Director/Study Principal Investigator).

Facility * **(FDAAA)**

- Name: Full name of the organization where the protocol is being conducted.
  (Limit: 254 characters)
  Examples: UCLA Eye Institute; Springfield Memorial Hospital
- City * **(FDAAA)**
- State/Province * **(FDAAA)**
- Postal Code
- Country * **(FDAAA)**

Recruitment Status * **FDAAA** - protocol accrual activity at a facility. Select one.

- Not yet recruiting: participants are not yet being recruited
- Recruiting: participants are currently being recruited
- Enrolling by invitation: participants are being (or will be) selected from a predetermined population
- Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled
- Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)
- Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume
- Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated
- Withdrawn: study halted prematurely, prior to enrollment of first participant

NOTE: Contact information is shown on ClinicalTrials.gov only for locations with status set to "Recruiting" or "Not yet recruiting".

Tip: When a trial's overall status changes to "Active, not recruiting," it is not necessary to change recruitment status for each location. Location recruitment status is only shown on ClinicalTrials.gov when Overall Status is "Recruiting".

Facility Contact * **(FDAAA)** (or Central Contact required)

- First Name
- Middle Initial
- Last Name * **(FDAAA)**
- Degree
- Phone * **(FDAAA)**: (or Email required) office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email * **(FDAAA)**: (or Phone required) electronic mail address of the facility contact person

Facility Contact Backup
Person to contact if Facility Contact is not available (i.e., a second contact person).

Investigators (at the protocol location)

- First Name
- Middle Initial
- Last Name
- Degree
- Role: Site Principal Investigator or Site Sub-Investigator (pick one)

Contact information character limits:

- First Name: 62 characters
- Last Name: 62 characters
- Degree: 30 characters
- Phone: 30 characters
- Phone Ext: 14 characters
- Email: 254 characters
- Affiliation: 160 characters

▼ 12. References

Citations
Definition: Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

PubMed Identifier
Definition: PubMed Unique Identifier (PMID) for the citation in MEDLINE
Example: 10987815

Citation
Definition: bibliographic reference in NLM's MEDLINE format (Limit: 2000 characters)
Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in

postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50

Results Reference?
Definition: Indicate if the reference provided reports on results from this clinical research study.

Links
Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. *Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.*

URL
Definition: complete URL, including http:// (Limit: 3999 characters)
Example: http://www.alzheimers.org/

Description
Definition: title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol. (Limit: 254 characters)
Examples:

> Click here for more information about this study: Clinical Trial of Eye Prophylaxis in the Newborn
>
> The Alzheimer's Disease Education and Referral (ADEAR) Center is a service of the National Institute on Aging

Available Study Data/Documents
Definition: Study data sets and documents that are being shared. Provide the following information for each:

Type
Definition: The type of data set or document being shared.

- Individual Participant Data Set
- Study Protocol
- Statistical Analysis Plan
- Informed Consent Form
- Clinical Study Report
- Analytic Code
- Other (specify)

URL
Definition: The web address used to request or access the data set or document. (Limit: 3999 characters)

Identifier
Definition: The unique identifier used by a data repository for the data set or document. (Limit: 30 characters)

Comments
Definition: Additional information including the name of the data repository or other location where the data set or document is available. Provide any additional explanations about the data set or document and instructions for obtaining access, particularly if a URL is not provided. (Limit: 1000 characters)

参考資料 3

Clinicaltrials.gov における登録レビュー方針

ClinicalTrials.gov Review of Protocol Submissions

Background

Protocol information must be clear and informative and information must be consistent with the ClinicalTrials.gov Protocol Data Element Definitions (DRAFT): http://prsinfo.clinicaltrials.gov/definitions.html. ClinicalTrials.gov reviews protocol information for apparent validity, meaningful entries, logic and internal consistency, and formatting. This document is intended to assist data providers in preparing registration records by providing an overview of ClinicalTrials.gov review criteria. This document is not comprehensive. It is the responsibility of the data provider to ensure that records are consistent with these criteria. The public posting of a registration record by ClinicalTrials.gov does not necessarily mean that all of these criteria have been met. At times, ClinicalTrials.gov may note problems and request revisions after a record has been posted publicly.

Registration Review Criteria

General

- Record is in English (with possible exception for the Official Title).
- Acronyms and abbreviations are spelled out fully (with acronym or abbreviation in parentheses) at least the first time they are used in the Protocol Section. Acronyms used to identify the study are entered in the Acronym data element.
- No spelling errors exist. Hint: The Spelling Tool on the "View Protocol Record" page may be used to identify possible spelling errors.
- No formatting problems exist, including any unreadable characters or symbols. Hint: Unicode, UTF-8 format, is the standard for ClinicalTrials.gov.
- In general, the Brief Title is in lay language and includes the condition and intervention evaluated in the study.
- Board approval (by an ethics committee) is required for all Interventional studies.
  - For trials with an Overall Recruitment Status of "Not Yet Recruiting," a Board Approval Status of "Submitted, Pending" or "Request not yet submitted" is acceptable.
  - Once participant recruitment begins, a Board Approval Status of "Approved" and the Review Board Name and contact information (either phone or email) is required.

Internal Consistency - Information must be consistent throughout the record.

- Overall Recruiting Status is consistent with Study Start Date and Primary and Study Completion Dates.
- Study Type is consistent with other information in the record (see Study Type below).
- Intervention Names are the same throughout the record (see Intervention Information below).
- Study Design data elements are consistent with Official Title and other information in the record.

Brief Summary and Detailed Description

- Information is provided in complete sentences and is not written in the first person.
- References are not provided in this section. All references must be entered in the Citation field.
- Compensation/reward information is not present.
- Results-type data ("results" or "conclusions" of the study) are not present. Results may be entered in the results section of the record (see additional information about entering results at https://prsinfo.clinicaltrials.gov/fdaaa.html).

Study Type - Designation of study as 'Observational' or 'Interventional' is consistent with other information in the record and with the ClinicalTrials.gov Protocol Data Element Definitions (DRAFT):

- Interventional
  - Definition: Studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.
  - Hint: Randomized studies are interventional. Studies with investigational drugs or devices are likely to be interventional.
- Observational
  - Definition: Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

Outcome Measures - The Primary and Secondary Outcome Measure Titles and Descriptions (if provided) are as **specific** as possible.

- The Outcome Measure information includes the name of the specific measure (e.g., Systolic Blood Pressure) and a description of the metric that will be used to characterize the measure (e.g., Change in Systolic Blood Pressure).
  - Hint: "Bioequivalence," "pharmacokinetics," and "pharmacodynamics" are not specific descriptions of an Outcome Measure because they do not specify by which measures bioequivalence, pharmacokinetics or pharmacodynamics will be assessed. Examples of Outcome Measure Titles to assess these parameters include:
    - "Area under the plasma concentration versus time curve (AUC) of 'drug x'"
    - "Peak Plasma Concentration (Cmax) of 'drug x'"
  - Hint: "Safety," "tolerability," and "feasibility" are not specific measures. Similarly, "Adverse events" by itself is not sufficient. "Number of participants with adverse events" is specific.
- The Outcome Measure information describes WHAT will be measured, not why it is measured.
  - Hint: Generally, verbs should not be included in the Outcome Measure Title.

Outcome Measure Time Frame - Each Outcome Measure includes a time point at which the outcome is assessed for the specific metric used. Most outcome measures will have one time point. If multiple outcomes are based on the same underlying measure (e.g., Outcome Measure Title "Change from Baseline in Hamilton Depression Rating Scale") assessed at different time points (e.g., "8 weeks and 12 weeks"), then each unique combination of measurement and Time Frame is entered as a separate Outcome Measure (e.g., "Change from Baseline in Hamilton Depression Rating Scale at 8 weeks" and "Change from Baseline in Hamilton Depression Rating Scale at 12 weeks").

- "Change" Outcome Measures – Generally two time points (e.g., "baseline and 8 weeks") are entered to indicate the time period over which the change occurred.
- Time-to-Event Outcome Measures – This measure describes plans to assess the time to occurrence of an "event" (e.g., "death"). The Time Frame should, at a minimum, include the estimated period of time over which the event will be assessed (e.g., "up to 100 weeks"). The Time Frame may also include information on how the event will be determined and over what estimated period of time (e.g., "From date of randomization until the date of first documented progression or date of death from any cause, whichever came first, assessed up to 100 months").
- Pharmacokinetic Outcome Measures (e.g., Cmax, AUC) – These assessments rely on multiple measurements over time and the Time Frame may include multiple time points describing the interval at which data are collected (e.g., "0, 1, 2, 3, 4, 6, 8, 12 , 24, 48, 72, 96 hours post-dose").
- Hint: "At follow-up" or "end of study" is usually not an adequate Time Frame. At a minimum, the Time Frame should include the maximum length of follow-up that is currently planned (e.g., "up to 3 years").
  - Exceptions are possible, for example, in measures that are assessed at the particular time the intervention is administered (e.g., "at time of surgery").

Conditions or Focus of the Study

- Only the primary disease or condition being studied is listed. If the focus of the study is not a disease, a brief description is provided (e.g., "Medical Errors").

Intervention Information

Each intervention is entered separately using the Intervention Type, Name, and Description data elements.

- **Intervention Names**
  - Drug Names: The generic name of the drug must be used, if available. If more than one drug name is being used for the same drug (e.g., a generic name and a brand name), clearly indicate that one drug is the same as the other. The preferred format is to include one drug name in parentheses next to the other drug name, for example: "Advil (ibuprofen)."
  - **The Other Intervention Names data element is not currently viewable on the public site; therefore the content of the record must be clear and consistent in the use of Intervention Names.** More than one drug name can be confusing to the public, particularly a patient audience.
  - Device and Other (non-Drug) Names: A specific device name or other descriptive name is provided with sufficient detail so it can be distinguished from other similar interventions.

- **Intervention Type**
  - List each Intervention Name and Intervention Type that is used in the study; each Arm may include more than one Intervention Type.
  - Procedures frequently involve a drug or device. Whenever possible, the other relevant Intervention Types used in the procedure (e.g., Drug, Device) are selected and specific Intervention Names are listed.
  - Each unique intervention is entered separately using the Intervention Type and Intervention Name data elements.

- **Arm Information** - Each intervention is assigned to the corresponding Arm.
  - Arm Type
    - "Active Comparator" or "Placebo Comparator" cannot be the only Arm Type for a "Single Group Assignment" study design. The presence of a "Comparator" suggests that there is more than one Arm (to what the "Active Comparator" is being compared).
    - If an intervention is assigned to an Arm, "No Intervention" is not an appropriate Arm Type.

Eligibility
- A list of key Inclusion Criteria and Exclusion Criteria is included.
- Criteria are bulleted (preferred format) or numbered.

Locations
- If Central Contact is provided, only City, State and Country of locations are required.
- If there is no Central Contact, additional information is required (contact number or email).

参考資料 4

EMA における　EudraCT におけるデータ登録に関する資料

Enhanced Form Logic Guidance

Implementation in EudraCT V8.1

Document Version 1.0
1st August 2011

Enhanced Form Logic – EudraCT V8.1

In EudraCT v8.1 When specific values are entered into certain fields in an entry form, this will also auto fill other relevant fields without requiring a manual input. The enhanced form logic is based on the following criteria:

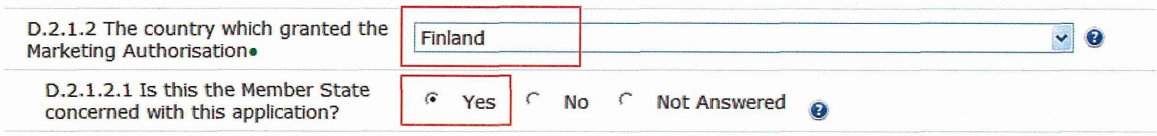
- *Auto-population of child/dependant fields with the contents of parent fields to make the form sections easier and quicker to fill in, reducing the amount of duplicate data entry*

- *Auto-population of child/dependent fields is only activated on initial data entry but subsequent changes/corrections of the parent field are not carried over to child fields. E.g A.1 Member state in which the submission is being made will be auto filled in D.2.1.2, Country that granted the MA, however if the user changes the value in A.1, the update will not be cascaded to D.2.1.2*

- *For subsequent changes/corrections, the child/dependent fields need to be updated manually – they do not change automatically. This approach is taken to avoid users having entered data changed or deleted without their knowledge*

Enhanced Form Logic – Example of auto population

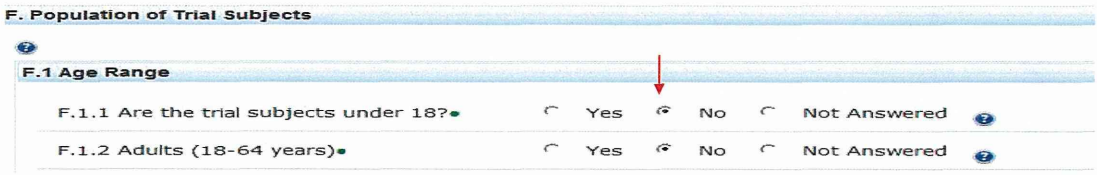
D.2.1.2 The country that granted the marketing authorisation and D.2.1.2.1 Is this MS concerned with this application is auto populated on the basis of A.1 Member state in which the submission is being made



Please note *if you change or update the entry in A.1 from Finland to some other country, the change will not be cascaded to D.2.1.2 / D.2.1.2.1 This update or correction will have to be entered manually as the logic is only supported on initial data entry.*

Enhanced Form Logic – Example of hiding non applicable questions

If F.1.1 Are the trial subjects less than 18 years answered = 'no', all sub questions upto F.1.1.6.1 are hidden.



These questions are displayed if F.1.1 = 'yes'

Enhanced Form Logic
Listing of Fields by CTA Section

Note: Please refer to the Clinical Trial Application (CTA) Form for field descriptions for field identifiers referenced in these slides

B.2 Legal Representative

• When the sponsor is located in a EEA country i.e. B.1.3.4 = EEA, the legal representative section B.2 could be hidden

C.1.1 And C.1.2 Sponsor Information/Legal Representative

Automatic load of sponsor information if the sponsor is also an applicant. Likewise auto population of legal representative information if the legal rep is also an applicant.

• If question C.1.1, value = Sponsor, the Applicant information should be auto-filled with the Sponsor information in section C.1.4.1 upto C.1.4.6. The info will be auto populated from B.1

• Likewise, if C.1.2 value = The Legal Representative, the Applicant information should be auto filled with the Legal representative information in C.1.4.1 upto C.1.4.6. The info will be auto populated from Section B.2

Section D.2

CTA sub questions dependent on a Yes answer to a parent/root question are hidden by default. They are displayed if the answer to the root question is Yes.

• D.2.1.1.4.1 should only be displayed if D.2.1.1.4 is answered Yes

• D.2.5.1. should only be displayed if D.2.5 is answered Yes

• D.2.6.1.1 and D.2.6.1.2. should only be displayed if D.2.6.1. is answered Yes

D.2.1.2.1

- *D.2.1.2.1 Is this MS concerned with this application should be automatically answered on the basis of A.1 MS in which the submission is being made and D.2.1.2 The country that granted the marketing authorisation.*

Section D.3

- *D.3.11.3.1, D.3.11.3.2, D.3.11.3.3, D.3.11.3.4, and D.3.11.3.5 should only be displayed if D.3.11.3 is yes*

- *D.3.11.3.5.1 should only be displayed if D.3.11.3.5 is answered Yes*

- *D.3.11.10.1 and D.3.11.10.2 should only be displayed if D.3.11.10 has been answered Yes*

D.3.6.1 And D.3.6.2

- *Routes of administration in D.3.6.1 And D.3.6.2 should automatically be included in D.3.7*

Section D.4, D.5, D.6 continued..

- *D.4.1.3.1 should only be displayed if D.4.1.3 is answered Yes*
- *D.4.2.2.1 should only be displayed if D.4.2.2 is answered Yes*
- *D.4.2.3.1 should only be displayed if D.4.2.3 is answered Yes*

- *D.5.4.1.1 and D.5.4.1.2 should only be displayed if D.5.4.1 is answered Yes*
- *D.5.4.2.1 should only be displayed if D.5.4.2 is answered Yes*
- *D.5.4.3.1 should only be displayed if D.5.4.3 is answered Yes*
- *D.5.5.3.1 should only be displayed if D.5.3.3 is answered Yes*

- *D.6.1.3.1 should only be displayed if D.6.3.1 is answered Yes*
- *D.6.2.2.1 should only be displayed if D.6.2.2 is answered Yes*
- *D.6.2.3.1 should only be displayed if D.6.2.3 is answered Yes*

Section D.7

- *D.7.4.1.1. should only be displayed if D.7.4.1. is answered Yes*
- *D.7.4.1.1.1. should only be displayed if D.7.4.1.1. is answered Yes*
- *D.7.4.5.1 should only be displayed if D.7.4.5 is answered Yes*

Section D.8

- *D.8.5.2.1 should only be displayed if D.8.5.2. is answered No*

Section E

- *E.7.1.1 to E.7.1.3.1 should only be displayed if E.7.1 answer is Yes.*

E.8.1

- *E.8.1 and E.8.2 sub-questions until E.8.2.4 should be hidden and only displayed when E.8.1. is answered Yes*

F.1.1 Less than 18 years

- *All sub questions dependent on F.1.1. upto F.1.1.6.1 should be hidden unless F.1.1. is answered Yes.*

G.2.5.4 And H.2.24

- *G.2.5.4 and H.2.2.4 should have automatically written the country in A.1.*

H.2.1

- *A1 Member state in which the submission is made should be automatically included in H.2.1 Name of Competent Authority*

Annex - Enhanced Form Logic

EudraCT V8 Behaviour

EudraCT Version 8 – Enhanced Form Logic System Behaviour
D.4, D.5, D.6, D.7

- *D.4 is only displayed if D.3.11.3.1 is answered Yes*
- *D.5 is only displayed if D.3.11.3.2 is answered Yes*
- *D.6 is only displayed if D.3.11.3.3 is answered Yes*
- *D.7 is only displayed if either D.3.11.3.4. or D.3.11.4 are answered Yes*

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