Init1dbw7.pm19 - Structured Eligibility Criteria

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Define structured eligibility criteria CDE

Use Case Number	Init1dbw7.pm19.1
Brief Description	Structured eligibility criteria allows for data to be evaluated against standard criteria in the form of a CDE to determine eligibility to a clinical trial. For example, the eligibility criteria may be that the subject must be male and the structured criteria would be gender equals male. This can be represented as a CDE with an operator and value, e.g. age >= 21.
Actor(s) for this particular use case	Metadata Specialist
Pre-condition **The state of the system before the user interacts with it**	None.
Post condition **The state of the system after the user interacts with it**	A structured eligibility criteria is encoded in a CDE.
V Steps to take **The step-by-step description of how users will interact with the system to achieve a specific business goal or function**	1. The Metadata Specialist creates a CDE to be used as structured eligibility criteria. 2. The Metadata Specialist adds the concepts that describe the data to be evaluated (e.g. age) 3. The Metadata Specialist adds the operator (e.g. greater-than or equals) 4. The Metadata Specialist adds the data to evaluate against (e.g. 30)
Alternate Flow **Things which would prevent the normal flow of the use case**	A wide variety of structured eligibility criteria can exist that ranges from mathematical operations to boolean operations to even more complex ternary and beyond operations.
Priority **The priority of implementing the use case: High, Medium or Low**	Medium.
Associated Links **The brief user stories, each describing the user interacts with the system for the one function only of the use case. There would potentially be a number of user stories that make up the use case.**	- Init1dbw7 - Structured Eligibility Criteria
Fit criterion/Acceptance Criterion **How would actor describe the acceptable usage scenarios for the software or service that meets the actor's requirement?**	Additional requirements need to be gathered to determine the range of operations and rules that can be encoded in structured eligibility criteria.

Evaluate structured eligibility criteria

Use Case Number	Init1dbw7.pm19.2
Brief Description	Once a set of structured eligibility criteria are encoded, a service should be able to evaluate that criteria against matching data. The data points themselves should reference the structured eligibility criteria CDE to which they refer.
Actor(s) for this particular use case	Cancer Researcher

Pre-condition **The state of the system before the user interacts with it**	A form of structured eligibility criteria is available.
Post condition **The state of the system after the user interacts with it**	Each eligibility criteria is evaluated against source data.
Steps to take **The step-by-step description of how users will interact with the system to achieve a specific business goal or function**	1. The Cancer Researcher inputs data for each structured eligibility criteria CDE. 2. The Cancer Researcher requests to have the data evaluated for eligibility. 3. The service evaluates each piece of data against each referenced structured eligibility criteria by applying the correct operator and evaluation data. 4. The service returns the eligibility results to the Cancer Researcher.
Alternate Flow **Things which would prevent the normal flow of the use case**	None.
Priority **The priority of implementing the use case: High, Medium or Low**	Low.
Associated Links **The brief user stories, each describing the user interacts with the system for the one function only of the use case. There would potentially be a number of user stories that make up the use case.**	• Init1dbw7 - Structured Eligibility Criteria
Fit criterion/Acceptance Criterion **How would actor describe the acceptable usage scenarios for the software or service that meets the actor's requirement?**	It is highly desirable that the results of each eligibility criteria is returned, but minimally the overall results (eligible or not) should be returned.