

## **SIP opinions on 11 ideas on innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers**

IHI received 11 almost-identical ideas from 11 separate organisations / individuals. As they are extremely similar, the SIP assessed them together and we are publishing their opinions together here, as follows.

Idea title: Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions

Reference numbers of the ideas: TI\_001225, TI\_001224, TI\_001223, TI\_001222, TI\_001221, TI\_001233, TI\_001232, TI\_001231, TI\_001230, TI\_001226

Idea title: Enrichment strategies for mental disorders using objective, quantifiable biomarkers towards the development of preventive, diagnostic or therapeutic discoveries

Reference number of the idea: TI\_001219

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001219

*Enrichment strategies for mental disorders using objective, quantifiable biomarkers towards the development of preventive, diagnostic or therapeutic discoveries*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001232 and TI\_001233. These are to be considered all together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001221

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001232, TI\_001233. These are to be considered together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001222

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001232, TI\_001233. These are to be considered all together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001223

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001232, TI\_001233. These are to be considered all together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001224

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001232, TI\_001233. These are to be considered together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001225

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions.*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001226, TI\_001230, TI\_001231, TI\_001232, TI\_001233. These are to be considered together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001226

*INNOVATIVE ENRICHMENT STRATEGIES FOR MENTAL DISORDERS USING OBJECTIVE, QUANTIFIABLE PREDICTIVE BIOMARKERS FOR THERAPEUTIC INTERVENTIONS*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001230, TI\_001231, TI\_001232, TI\_001233. These are to be considered together.



## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001230

*Innovative enrichment strategies for mental disorders using objective, quantifiable, predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001231, TI\_001232, TI\_001233. These are to be considered together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001231

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001232, TI\_001233. These are to be considered together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001232

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001233. These are to be considered together.

## Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI\_001233

*Innovative enrichment strategies for mental disorders using objective, quantifiable predictive biomarkers for therapeutic interventions*

### Overall opinion

The SIP is of the opinion to keep the idea for consideration with a few scoping considerations.

The idea is interesting because it addresses a high unmet need but is lacking specific objectives in relation with which gaps are addressed. Mental health diseases are complex and concern a potentially very large population, which questions the feasibility around the follow up of very big cohorts of patients.

Enrichment strategies should address the optimisation and acceleration of biomarkers validation, for instance by considering multi-omics (e.g., for a specific mental disease), imaging and other digital markers. This should also include the necessary regulatory pathway, as well as linking with effective implementation and integration of predictive biomarkers in healthcare systems.

Of note: The idea being similar to the following other idea(s): TI\_001219, TI\_001221, TI\_001222, TI\_001223, TI\_001224, TI\_001225, TI\_001226, TI\_001230, TI\_001231, TI\_001232. These are to be considered together.