D5.2 Scientific Advice Letter on the validation of biomarkers

PRISM 2 – GA 101034377
Psychiatric Ratings using Intermediate Stratified Markers 2

WP 5 Ethics and engagement with regulatory groups, agencies and other stakeholders

Lead contributor	Annalisa Marotto 14 BI, Martien Kas 01 RUG
	annalisa.marotto@boehringer-ingelheim.com ; m.j.h.kas@rug.nl
Other contributors	Renate Kat 01 RUG

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Deliverable type	R
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	V1	18.05.2021

Document History

Version	**Date**	**Description**
V1.0	24.06.2022	First Draft

Publishable Summary

Preparatory activities for a CHMP Qualification Advice procedure for Behapp have been initiated. This EMA procedure starts with the upload of a complete draft dossier in the EMA IRIS platform at the time of application,. A “letter of intent” is not foreseen, differently from the FDA Qualification process which starts with submission of such a letter.

Prerequisite for the submission is the availability of a Research Product Identifier (RPI) which needs to be requested prior to approaching the EMA for qualification of a new technology which has now been completed and confirmed by EMA.

Deliverable report

Preparatory activities for a CHMP Qualification Advice procedure for Behapp have been initiated. This EMA procedure starts with the upload of a complete draft dossier in the EMA IRIS platform at the time of application. A “letter of intent” is not foreseen, differently from the FDA Qualification process which starts with submission of such a letter.

Prerequisite for the submission is the availability of a Research Product Identifier (RPI) which needs to be requested prior to approaching the EMA for qualification of a new technology. Boehringer Ingelheim and Rijksuniversiteit Groningen prepared the Research Product Identifier (RPI) request form that has been submitted to EMA.

A RPI for Behapp based novel digital efficacy endpoint for social functioning has been issued by the EMA Scientific Advice Support at EMA on June 3rd 2022 - see the request form in appendix 1 attached.

Conclusion

A Research Product Identifier for Behapp based novel digital efficacy endpoint for social functioning has been issued by the EMA Scientific Advice Support at EMA on June 3rd 2022.

Acknowledgement

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Appendix 1 – Attached PDF with completed RPI request form

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Research Product Identifier (RPI) request form

(for technologies, methodologies or multiple products for Scientific Advice)

Please complete all parts of the form and send to: scientificadvice@ema.europa.eu
Notes:

1. if you intend to apply on behalf of an organisation, please put the Location ID of the organisation from SPOR/OMS in the first box (you will need affiliation to that organisation to see the RPI).
2. Please use this form only for a technology, methodology or multiple medicinal products. An RPI for an single medicinal product should be requested via IRIS.

EMA registered Username (individual users) or Location ID from OMS/SPOR* e.g. LOC-number (organisations)	Boehringer Ingelheim International GmbH; LOC-100018243
Address of the organisation (linked to LOC-number)	Binger Strasse 173 55216 Ingelheim Am Rhein Rhineland-Palatinate Germany
EMA account registered email (applicant)*	**ozlem.ozdemir@boehringer-ingelheim.com**

Name of the products/ technology / method* *(max 120 characters)*	**Behapp based novel digital efficacy endpoint for social functioning**
Human or/and Veterinary	**human**

Products/ Technology/ Development method/ Multiple products* *click on 'choose an item' and select one from the dropdown list below*	
Method/methodology (e.g. stats, manufacturing, software, biomarkers, validation)	
If "other" please specify	Behapp based novel digital efficacy endpoint for social functioning

*** Mandatory fields**

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific background	
Mode of action* *(max. 100 words)*	Behapp is a smartphone application developed at the University of Groningen, the Netherlands, that, once installed, passively tracks the use of the communication apps (e.g. the number of phone calls, SMS messages, email and social networks), geo-localization and WiFi connectivity over several weeks, representing particular behavioural aspects of social functioning. It is planned to use the measurements performed by Behapp as an efficacy endpoint for social functioning in clinical trials.
Notes	**An ITF briefing meeting was held on this topic on June 17, 2019. Please note that the developer of Behapp is the University of Groningen in the Netherlands. Boehringer Ingelheim is supporting the regulatory activities related to the qualification procedure.**

Therapeutic areas: please tick all relevant (at least one)

Tick all that apply	Therapeutic area
☐	Blood and lymphatic system disorders
☐	Cardiac disorders
☐	Congenital, familial and genetic disorders
☐	Ear and labyrinth disorders
☐	Endocrine disorders
☐	Eye disorders
☐	Gastrointestinal disorders
☐	General disorders and administration site conditions
☐	Hepatobiliary disorders
☐	Immune system disorders
☐	Infections and infestations
☐	Injury, poisoning and procedural complications
☐	Investigations
☐	Metabolism and nutrition disorders
☐	Musculoskeletal and connective tissue disorders
☐	Neoplasms benign, malignant and unspecified (incl. cysts and polyps)
☐	Nervous system disorders
☐	Pregnancy, puerperium and perinatal conditions
☐	Product issues
☒	Psychiatric disorders
☐	Renal and urinary disorders
☐	Reproductive system and breast disorders
☐	Respiratory, thoracic and mediastinal disorders
☐	Skin and subcutaneous tissue disorders
☐	Social circumstances
☐	Surgical and medical procedures
☐	Vascular disorders

Enabling technologies/ innovation: please tick all relevant (at least one)

Tick all that apply	Enabling technology	(Parent Term)
☐	Other innovation aspect / enabling technology	***(please specify in notes)***
☐	Nanotechnologies	Directly product-related
☐	Synthetic biology	Directly product-related
☐	Genetically modified organism(s)	Directly product-related
☐	Novel biomarkers, omics	Development-related: clinical
☐	Medicines for tropical diseases	Development-related: clinical
☐	Biodefense/biowarfare	Development-related: clinical
☐	Biomaterials	Associated medical devices
☐	Matrixes	Associated medical devices
☐	Other associated medical device	Associated medical devices
☐	Printing	Advanced manufacturing
☐	Bedside/point of care manufacturing	Advanced manufacturing
☐	Mobile/portable manufacturing	Advanced manufacturing
☐	Distributed manufacturing	Advanced manufacturing
☐	Transgenic technologies	Advanced manufacturing
☐	Novel/uncommon excipient	Other ingredients
☐	Adjuvant	Other ingredients
☐	Pharmacological chaperone	Other ingredients
☐	Bioenhancer	Other ingredients
☐	Photodynamic product	Smart materials in active substance(s)
☐	Other smart/advanced material	Smart materials in active substance(s)
☐	3D printing	Advanced manufacturing
☐	Targeted release to specific site(s)	Delivery methods
☐	Controlled-release technologies	Delivery methods
☐	New/uncommon pharm. form or route of admin.	Delivery methods
☐	Genome editing - deletion	Genome editing
☐	Genome editing - replacement	Genome editing
☐	Genome editing - regulation	Genome editing
☐	Human cell based in vitro models	Human cell-based
☐	Human stem cell in vitro models	Human cell-based
☐	Organoids	Non-clinical development: other
☐	Avatar, nude and humanised mice	Non-clinical development: other
☐	Physiologically-based pharmacokinetics	Non-clinical development: other
☐	Other in silico models	Non-clinical development: other
☐	Extrapolation proposed	Methodology of clinical trials
☐	Platform/Umbrella/basket trials	Methodology of clinical trials
☒	Novel endpoints	Methodology of clinical trials
☐	Bayesian designs	Methodology of clinical trials
☐	Adaptive designs	Methodology of clinical trials
☐	Monitoring devices/sensors/systems	Digital healthcare
☐	Closed loop systems	Digital healthcare
☐	E/m-health	Digital healthcare
☐	Big data analysis	Novel data sources
☐	Real world data analysis	Novel data sources