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ANNEX-(C)

Award "Digital Medicine and Digital Therapeutics"

(Award category no. 8)

The present annex only applies to award category no. 8 (Digital Medicine and Digital Therapeutics) and supplements the information provided in the main document (Prix Galien Italy Call for Applications 2021, published on www.prixgalien.it), which should be consulted for more general indications.

Definition of Digital Medicine and Digital Therapeutics

This award is addressed to Digital Medicine products, defined herein as evidence-based software, and possibly hardware, solutions devised to perform measurements or interventions capable of promoting human health. It includes Digital Therapeutics (see below), intended as a subset of Digital Medicine interventions based on clinical trials. Some examples of products are provided below:

	Type of product	Example
1	for measurement	Digital diagnostics (software-driven technologies for detecting or confirming a clinical/pathological condition) Digital monitoring (e.g., tools for detecting voice or other digital biomarkers of disease) Assessment of clinical outcome (e.g., assessment of the patient's well-being)
2	for intervention	Digital therapeutics (therapeutic interventions developed through randomized controlled clinical trials, in which the element responsible for the clinical effect is represented by an algorithm rather than by an active ingredient of synthetic chemical or biological origin) Digital Support Tools, digital interventions capable of optimizing medical, pharmacological, therapeutic, rehabilitative or preventive interventions

3	Combined measurement & intervention	Digital component integrated with a chemical or biological active ingredient Ingestible sensors (digital pills) Connected drug-dispensing tools (e.g., insulin pumps) Digital devices that measure and intervene simultaneously, without requiring human intervention/supervision (e.g., pacemakers, cochlear implants)

Entry requirements – eligible products

- Digital Medicine and Digital Therapeutics products that have received approval by at least one regulatory body or competent authority of any country (including but not limited to FDA, ANSM, BfArM, AEMPS, MHRA, Swissmedic, Notified bodies), in relation to the product's specific purpose of use. Products not yet approved by EMA, AIFA or the Italian Ministry of Health are therefore eligible for entry.

Selection of the winner of "Digital Medicine and Therapeutics" award

- Assessment of the "Digital Medicine and Digital Therapeutics" entries (award category no. 8) will be carried out by an *ad hoc* expert committee (see www.prixgalien.it), based on the criteria listed at the end of this document. The winners will be selected by this Committee.

Required documentation and deadlines for application

- Companies wishing to enter the competition should send Springer the following documents: (1) Cover letter, (2) Application dossier, (3) Materials for communication with the press. These documents should be prepared following the instructions provided in the present annex
- The documentation must be sent by 23:59 hours (CEST, Central European Summer Time) of 15 April 2021 via e-mail via e-mail (as *doc *docx *pdf file attachments) to the following address: shcmilan@springer.com with a courtesy copy to eleonora.zanaboni@springer.com and indicating in the subject line: "Prix Galien Italy 2021 Application".

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Outline for preparing the entry documentation

1. COVER LETTER (up to 3500 characters including spaces)

- Name of the product
- Main properties of the product and its innovative features
- Information on the state of approval in Italy or worldwide
- Name, surname and contact details of the person in charge of the application (e-mail address, at least one phone number)
- Consent to publish the pharmaceutical company's logo on the Prix Galien Italy website (if consent is provided, please attach to the application dossier the logo image to be used).
- Place, date and signature

2. APPLICATION DOSSIER

2.1. *Characteristics*

- Therapeutic indications and possible recommendations for use
- Manner of use by target users
- Innovative features also as compared with conventional practices in managing the condition
- Place in therapy

2.2. *Development Plan and Research Team*

- Clinical needs and scientific rationale underlying the development of the product
- Elements of innovativeness
- Brief description of the development plan and application for approval by regulatory bodies, if applicable
- Brief description of the research/development team(s) and mention of the contribution of any Italian researchers/developers involved

2.3. *Clinical Development Plan: Methods and Research Groups Involved*

- Detailed description of the clinical development plan (with special emphasis on the description of pilot and confirmatory studies, and acceptability and usability tests).
- Detailed analysis of any innovative research methods implemented in the studies and forming part of the clinical development plan.
- List of publications (especially original research papers, but also reviews or meta-

analyses) published in indexed peer-reviewed journals and addressing the results obtained by studies conducted within the clinical development plan or by independent studies

- Mention of any Italian clinical research groups involved in the studies

2.4. Therapeutic Efficacy

- Provide, preferably in table form, the efficacy results of the main clinical trials investigating the digital active ingredient.

3. MATERIALS REQUIRED FOR COMMUNICATION WITH THE PRESS

1. Name, surname and contact details of the person in charge of communication with the press (e-mail address and at least one phone number)
2. Text presenting the Digital Therapeutics product being entered for the award (length: 800 characters including spaces) to be used in communications with the press and published on the website www.medicioggi.it. The text should contain the following information:
    a. Name of the product
    b. Indications
    c. Notes on its operation
    d. State of approval in Italy or worldwide
3. Copyright-free illustration to accompany the presentation text, to be freely shared with the press (an artistic and/or schematic rendering of the product's operation or use is suggested)

Assessment criteria adopted by the jury

Digital Therapeutics

- Compliance and completeness of the dossier
- Originality/innovation
- Clinical impact
- Scientific impact
- Social impact
- Literature references