Call for Projects:  
Digital Markers for Rare Diseases

OBJECTIVES

Novel technologies of e-health for rare diseases represent a major opportunity that could revolutionise its medical practice, treatment as well as the quality of life of the patients. In this context, Kyomed launches an ambitious Call for Projects with the aim to boost the momentum of e-health development in rare diseases which affect today 3 million people in France and 30 million in Europe with 7000 to 8000 pathologies.

The objective of this Call for Projects is to develop, valuate and promote e-health projects targeting one or more rare diseases. Within the framework of its partnership, Kyomed and Eurobiomed propose to facilitate the development of novel digital markers* for rare diseases. In particular, Kyomed wishes to demonstrate the scientific and/or medical merits of these markers in complementing the use of classic molecular markers in order to reveal their full benefits in the care of rare disease patients. These imprints combining digital and molecular markers are one of the major stakes in the medicine of the future.

*a digital marker is defined as a measurable characteristic that is personal or linked to a person obtained via one or several connected and/or mobile solutions. This characteristic is indicative of a physiological and/or pathological state, or a state linked to the environment of the person.

TO WHOM THIS CALL FOR PROJECTS ADDRESSES

You are a clinician, an academic or you are from the industry;

You have an idea, an e-health project that focuses on the use of one or more digital markers for one or several rare diseases;

You are looking for complementary competencies for your project, a scientific, medical, technical or legal support, a network of e-health experts or a clinical network; you need assistance in seeking financing.

Take the opportunity of this Call for Projects “Digital Markers for Rare Diseases” and work together with us for the improvement and innovation in rare diseases!
Example: a project could show interest in the measurement by an e-health solution of new physiological data in rare disease patients; For example, the constant biological monitoring of a connected cutaneous patch that measures the concentration of relevant substances (as much as the circulating concentration is correlated to its interstitial concentration, as demonstrated for glycaemia), allowing the regulation and monitoring by a connected object of an health episode such as recurrent comitial seizures in children with rare epilepsy with the aim of improving the treatment.

KYOMED

Created in April 2014, Kyomed was the winner of the Programme Investissements d’Avenir in France in 2013. The vocation of Kyomed is to accelerate and optimize the development of innovative solutions in the field of e-health and personalized medicine. The approach of Kyomed is founded on the paradigm of the 4Ps in medicine: predictive, preventive, personalized and participative. Kyomed pilots multi-partner projects by drawing on its network of scientific, technical and medical experts. The team of Kyomed accompanies its clients from research to commercialization of their solutions and offers expert services in 3 areas:

- **e-health**, in proposing validation of usage and acceptability of e-health innovative solutions according to the agile methods of Living Lab, Kyomed provides technological and regulatory affairs support towards industrialization while taking into account economic models that ensures the viability of the solutions and clinical validation of their health benefits. Kyomed also integrates major players of e-health in its national and international networks. Hence, the proposed solution for a project can be evaluated in real life by the respective users and improvements can be made based on feedback directly from the field. In fact, the questionnaires deployed by Kyomed aims at qualifying and maximizing the potential of a solution in terms of acceptability, appropriation by health professionals, positioning within the care system as well as the economic model.

- **Identification and clinical validation of molecular biomarkers and digital markers** for diagnostics, prognostics and personalized medicine. Kyomed invests particularly in the integration of molecular data and digital data within the imprints for the personalisation of patient care. Kyomed is capable of rapidly mobilising the necessary competencies and expertise for projects on the discovery of biomarkers. Our platform consists of laboratories and experts in genomics, proteomics and histology which can be put in service for these projects.

- **Health data treatment**, in assuring an intelligent exploitation of complex heterogeneous data, bio-statistical analysis, biomathematics, the development of algorithm and modelling for medical decision aid. Kyomed’s team possesses several years of expertise in methodology and health data treatment ensuring quality, efficiency and relevance of the responses to the different questions of interest. The combination of digital markers and classic biomarkers requires statistical algorithms and/or new statistical models. The expertise of Kyomed hence plays a key role in the exploration and optimization of these digital and biological signatures in rare diseases.
**EUROBIOMED**

Eurobiomed, the regional competitive hub for healthcare has been active over 10 years in the development of diagnostic tools and therapeutics in order to advance the care of patients suffering from rare diseases. Eurobiomed organises a biannual national event “RARE” that assembles industrial players, researchers, clinicians and patients’ associations. In 2015, 375 participants took part in the event. Eurobiomed has within its 250 members 60 organisations working on rare diseases. Since its creation, Eurobiomed has supported 14 R&D projects representing an investment of € 25.8M.

**CRITERIA OF ELIGIBILITY**

This Call for Projects is open to all individuals (independent of their affiliation), all clinical entities whether they are academic, industrial or associative, that are engaged in the research, diagnostic, monitoring or treatment of one or more rare diseases.

All projects aimed at the use of novel e-health technologies and digital markers for rare diseases will be examined. These digital markers can also, but not necessarily, be combined with one of more existing or novel molecular biomarkers.

The targeted projects are those with at least the first clinical experimentation underway (all pathologies included):

- All projects based on one or more digital markers having demonstrated its usage in a small number of rare disease patients;
- All projects based on one or more digital markers having demonstrated its clinical proof in another pathology but presents an application potential in rare diseases

Preference will be given to projects with a time-to-market of 12 to 18 months.

**PROJECT SELECTION**

All submitted projects will be evaluated by a jury with medical, clinical, industrial, ethical and financial expertise.

The panel is represented by:

- Pfizer
- Sanofi Genzyme
- Prof. Paul Landais, physician in public health, and specialist in rare diseases
- Eurobiomed
- Kyomed
SELECTED PROJECTS

One or more projects can be selected. The following aspects will attract particular attention of the jury:

- Projects providing scientific demonstration of the benefits of digital markers complementing classical markers;
- Projects satisfying unmet medical needs, technologies breaking new grounds or providing significant improvement to existing solutions;
- Projects presenting real benefits to patients and/or the medical profession in the care and/or quality of life of rare disease patients;
- Projects that are original and innovative

The selected projects will be supported by Kyomed and Eurobiomed on different levels according to their needs.

Kyomed offers the winners the following according to the needs:

- A regulatory audit by experts to an equivalent of €1,500 net;
- Service equivalent to the worth of €2,500 net of Kyomed’s Living Lab for the evaluation of user needs;
- 2-man days’ work to put in relations with reference clinical networks for access to national patients’ cohorts;
- 1-man day’s work for the preliminary evaluation by experts in the methodology of data treatment;
- 2-man days’ work for the analysis of commercial potential and positioning of the project, identification of industrial partners;
- Publicity of the project – opportunity for the initiators of the selected projects to present their projects at an important scientific or technical event.

In addition, Eurobiomed offers the winners the following according to the needs:

- Support in the search for public or private financing;
- Support in the strategic development of the project: an audit by the competitive units of Eurobiomed, a service of high added-value for the development of healthcare companies (1-man day in the presence of Kyomed);
- Put in relations with national players in rare diseases;
- Publicity of the project – through the tools of communication of Eurobiomed on social media (Twitter, LinkedIn and website). An invitation for the winner to participate in rare disease events. Information of the winners within the rare disease network of Eurobiomed.

DATES AND DÉADLINES

The Call for Projects is open on the occasion of the 9th international rare disease day, on 29 February 2016.
Persons who wish to participate in this Call for Projects are invited to submit in the first place a letter of intention (a 3 to 4-page document, to be downloaded from the website www.kyomed.com).

For the letters of intention that are declared eligible by the jury, the initiators will be asked to submit a full document detailing the project (10 to 20 pages) to be downloaded on the website.

The jury will retain the best projects for a final audition to be followed by the nomination of the final winners.

**Dates and Deadlines:**

- Submission of letter of intention on line (www.kyomed.com): 29/02/2016 to 04/04/2016
- For the eligible projects: submission of full document 21/04/2016 to 27/05/2016
- Announcement of selected projects for Grand Audition: 17/06/2016
- For the projects selected for the Grand Audition: audition in Paris 27/06/2016
- Announcement of the winners: 30/06/2016

**Contact**

Please send your submission to: contact@kyomed.com

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