A multidisciplinary approach to the identification of BIOmarkers of MIGraine: a proof of concept study based on the stratification of responders to CGRP monoclonal Antibodies

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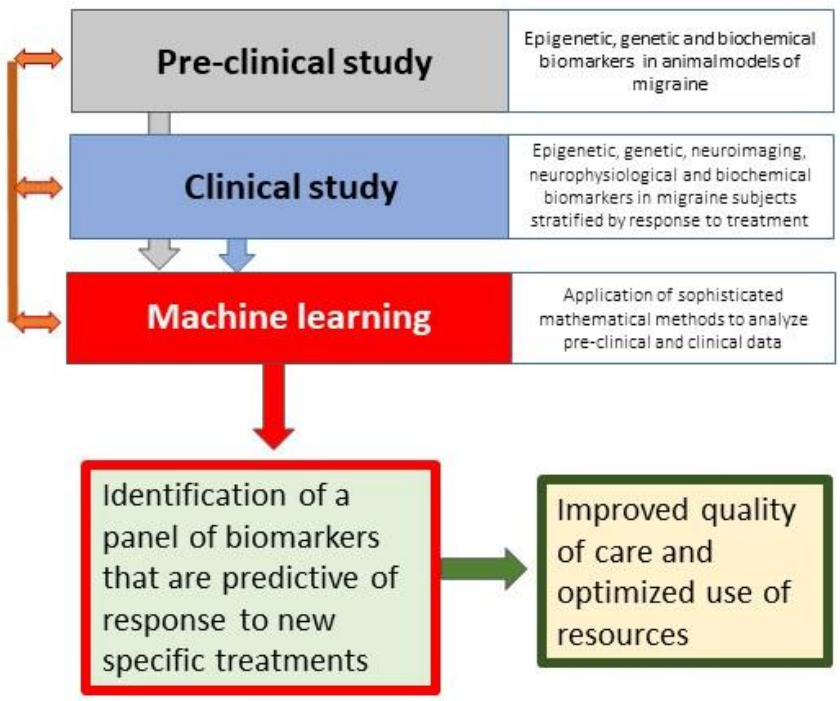
Migraine is one of the most prevalent conditions in medicine, affecting nearly 15% of the general population, and the second highest cause of disability worldwide. It afflicts mostly women, imposing a high burden on sufferers and an astronomical cost on healthcare systems. Up to 3% of the general population suffers from a very aggressive and drug-resistant form: chronic migraine.

So far, only a few drugs have proved effective in reducing the burden of chronic migraine, but only in a limited portion of patients and with considerable side effects. Very recently, a new class of drugs has become available to migraine sufferers in Europe: the monoclonal antibodies against a molecule called *calcitonin gene-related peptide* (CGRP), which plays a crucial role in the migraine attack. These drugs have shown an extraordinary effect, abating the number of monthly migraine days by more than 75%, but not in all patients. Moreover, this new cure is very expensive and doctors do not have tools to identify, beforehand, the patients who will benefit from the treatment.

BIOMIGA will identify disease-associated factors (so-called *biomarkers*) that may predict the response to treatment using a combined approach formed by 3 components:



The discoveries generated by the BIOMIGA project will provide the basis for an extremely innovative, personalized approach to the treatment of migraine: **the right drug to the right patient**.
This approach will dramatically improve the quality of care of migraine sufferers - so far based on a trial-and-error approach - limit their exposure to ineffective and poorly tolerated drugs, and contribute to rationalize the use of resources.

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