Case Study | 7th September 2022

Real-time mass pre-screening to identify eligible patients for evaluating the effect of a dietary supplement on glucose and lipid homeostasis in subjects with dysglycemia

Patient Identification | Patient Recruitment | IVD Clinical Performance | Data Management

The Case

In order to identify eligible patients for the evaluation of the effect of a dietary supplement on glucose and lipid homeostasis in subjects with dysglycemia, a pharmaceutical company requested our services in order to pre-screen patients meeting the following inclusion criteria:

- Patients with a risk to develop severe SARS-CoV-2,
- Presenting comorbidities (such as diabetes, heart disease, hypertension),
- And/or aged +65.

The Challenges

Regulatory expertise for the detailed description of the digital tools used for pre-screening and the related inclusion and exclusion criteria in the protocol and its submission to the ethics committee.

Identification within our network of routine laboratories in Paris and Lille of eligible patients meeting the inclusion/exclusion criteria.

Study design on our routine digital patient management tool and codified integration of eligibility criteria (ICD10, ATC, LOINC) as well as inclusion questions.

Coordination between the different stakeholders to transmit the eligible patient's personal data to the principal investigator for potential inclusion in the clinical trial.

How We Responded

Establishment of an expert working group dedicated to the project (field biologists, clinical research associates, a project manager, and a data manager).

Implementation of the study in 16 laboratories of our medical biology network whose RWDs meet the eligibility criteria of the study.

Development of an inclusion tracking portal broken down by profile & region for the sponsor, CRA and PIs.

Pre-screening of 1507 patients and identification of 90 patients meeting the pre-screening criteria in 2 months - which is twice as fast as the time estimated by the sponsor.

Top Takeaways

Fast ethical committee approval allowing this screening process with our network of Labs.

Quick start to design and implement the study in the field with a proactive involvement of the laboratories' staff.

Flexible and agile solution to adapt to the changes in the sponsor's inclusion criteria that occurred in the middle of the inclusion period.

E-signature on-site allowing to collect and share patients' personal data to the research center in real-time.

Timeline

Feb '21	Apr '21	Apr '21	Apr '21 – Jun '21 (2 months)	Jun '2021
Submissions to ethical committee	Start up	First inclusion	Inclusion period	Final report

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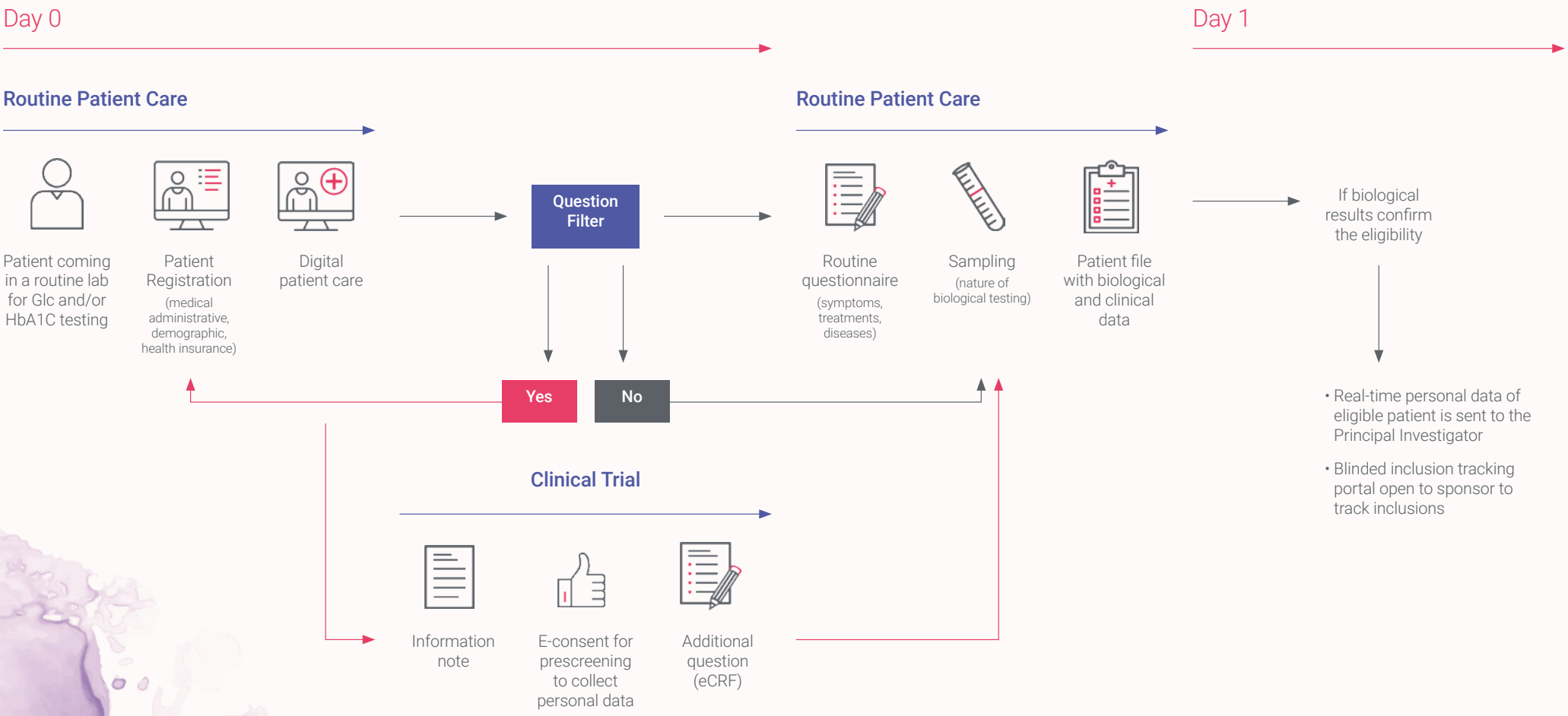
Overview of Study Process:



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