

"eHealth Innovation and Clinical Research"

Brussels, the 7th of November 2018



Confidential 1

- 1. Arithmos in a shell
- 2. Clinical Trials: a complex arena made of processes, technology, rules and responsibility
- 3. Technology and processes understanding



Arithmos is an Information Technology & consulting provider focused on Life Sciences Industry



Arithmos provides innovative IT solutions to clients with a specific focus on the Life Sciences value chain. Our comprehensive approach leads us to deliver IT products, services and consultancy.



Paolo Morelli Founder & CEO



Emilio Vandelli Managing Director



Silvia Gabanti Service Delivery Manager



Romina Zanier
Quality Assurance
Senior Manager



Davide Erbisti



Certifications





Partnerships



Our History

2010 <

Arithmos is founded in **Verona**, born from CRO's IT Department

2012

Arithmos acquires Symphony EDC Platform

2014

ArithmosCentrum PPM software is launched onto the market

2016

Launch of Argus Blueprint pharmacovigilance system

2017

Launch of SYNClevy, web-based Extended PPM platform

2017

Investment in Innovation Sprint, a consulting agency of innovation experts in ICT and Health



Arithmos is part of a group of companies reporting to PM Holding



Arithmos

IT company which provides IT products, services and consultancy in specific business areas: Life Science, R&D and Professional Services.

Est. 2010



CROS NT

CRO specialized in clinical data services data management, biostatistics, programming, medical writing and consultancy.

Est. 1992



seQure Life Sciences

Pharmaco / Devicevigilance, QA, CSV and Regulatory Affairs services for drug & device companies.

Est. 2017 (Previously PM Clinical from 2014)

Other participations



Kubo Recruitment

Staff recruitment company focused on matching talent with client needs in the Life Sciences sector.

Est. 2012



Tech company that offers edge technological services and products to organizations that seek to pivot and add value to their offering in the digital era.



Locations: the Group has offices in Italy, UK, Germany, Belgium, USA and India

Clinical Trials: processes, technology, rules and responsibility.

Given a Standard Clinical Trial Workflow...

PROTOCOL SITE SITE **PATIENT STUDY TREATMENT** DATA **STUDY ANALYSIS REPORTING RECRUITMENT** DEVELOPMENT **SELECTION** INITIATION CONDUCT TIME **CLEANING CLOSEOUT**

... many stakeholders, internal and external,

... many needs and requirements,

... one goal!





Clinical Trials: processes, technology, rules and responsibility.

Given a Standard Clinical Trial Workflow...



Which is the goal?

Getting "positive" and reliable results!







Digitalization and process automation are going to change the rules of the game

Given a Standard Clinical Trial Workflow...



What is client asking for?

- How to improve performances in Clinical trials with Technology?
- How to better involve patients?
- How to better address investments?

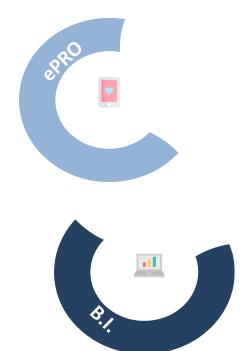




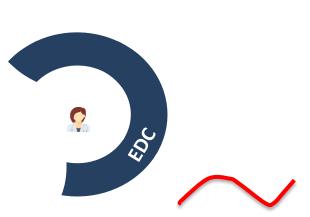
Given a Standard Clinical Trial Workflow...



Many systems not interconnected...









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Given a Standard Clinical Trial Workflow... it is needed a 360° perspective in the trial management

PROTOCOL SITE SITE **PATIENT STUDY** DATA **TREATMENT STUDY ANALYSIS** REPORTING **DEVELOPMENT SELECTION INITIATION RECRUITMENT** CONDUCT TIME **CLEANING CLOSEOUT**

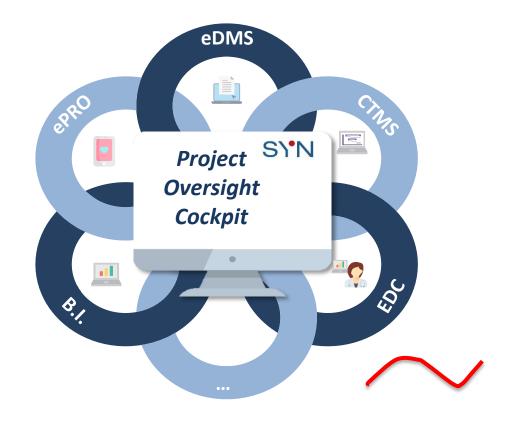
On June 2017 **ICH GCP E6 (R2)** entered into force, introducing new guidelines aiming at an increase in the responsibility of the Sponsor concerning the activities outsourced to the CROs.



5.2.2. Addendum

The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s).



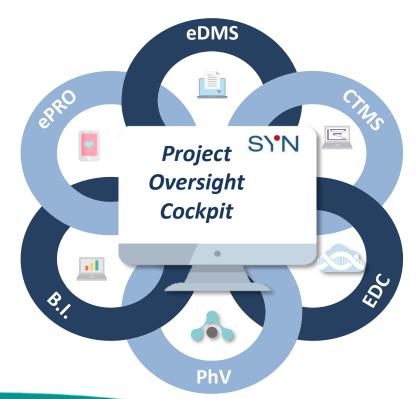




Given a Standard Clinical Trial Workflow... it is a need to keep the patient at the center

PROTOCOL SITE SITE **PATIENT STUDY TREATMENT DATA STUDY ANALYSIS REPORTING DEVELOPMENT SELECTION** INITIATION **RECRUITMENT** CONDUCT TIME **CLEANING CLOSEOUT**

Company Centric Platform





mHealth and IoT platform, ...



..., a unique opportunity to create a link between researcher and patient!





Given a Standard Clinical Trial Workflow... it is a need to keep the patient at the center of trial

PROTOCOL SITE SITE **PATIENT STUDY** DATA **TREATMENT STUDY ANALYSIS REPORTING DEVELOPMENT SELECTION** INITIATION **RECRUITMENT** CONDUCT TIME **CLEANING CLOSEOUT**



eClinical platform

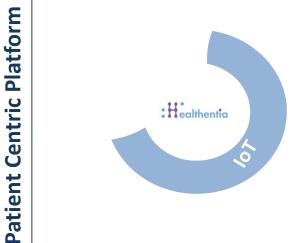
It is a data management cloud platform that captures patient and clinical outcomes from mobile, medical and IoT devices. Using a patient-centric app, it can be integrated with Project Oversight Platform.

Main Features



- Enhanced patient motivation and retention, giving rich insights;
- Richer datasets and Real World Data to enhance overall trial quality;
- eRecruitment for a more efficient enrolment of patients;
- Artificial Intelligence features to support patient/sponsor interaction (e.g. patient coaching);
- Empowers the Healthcare industry with an integrated solution to deliver patient-centric, more effective and predictive Healthcare

mHealth and IoT platform, ...



..., a unique opportunity to create a link between researcher and patient!





Given a Standard Clinical Trial Workflow... it is a wish to have data and KPIs to anticipate trial trends

SITE **STUDY DATA PROTOCOL** SITE **PATIENT TREATMENT STUDY ANALYSIS** REPORTING **DEVELOPMENT SELECTION INITIATION RECRUITMENT** CONDUCT TIME **CLEANING CLOSEOUT**

mHealth and IoT platform, ...

Patient Centric Platform

September 1997

Patient Centric Platform

Open 1997

Patient Centric Platform

..., a unique opportunity to create a link between researcher and patient!



- Real world evidence,
- Big data ,
- «On line connection»,
- Interactive relationship sponsor-patient,
- •



Investment management!





Given a Standard Clinical Trial Workflow... it is all a FIL ROUGE from operations to finance management thanks to a proper understanding and application of Digital Technology

PROTOCOL SITE SITE **PATIENT STUDY TREATMENT** DATA **STUDY ANALYSIS REPORTING SELECTION** INITIATION **RECRUITMENT** CONDUCT **CLEANING CLOSEOUT DEVELOPMENT** TIME

GXP rules Patient Centricity

Operative Needs

Investment Management





Thank You!

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