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Microservices-Based Architecture to Support the Adaptive RECORDS-Trial

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Abstract. Information systems used by platform trials should handle changes that are not predefined. Unfortunately, the technical architecture of most existing clinical data management systems (CDMS) do not support changes to be incorporated into an ongoing trial. Adaptive clinical trials need advanced architectural solutions setup to enable biomarker stratification and enrichment strategy necessary for the adaptive clinical trial operation. This short paper presents the microservices-based architecture solution that is used to run and support the adaptive RECORDS-Trial.

Keywords. Platform Trials, Adaptive Clinical-Trial, Biomarker stratification, Microservices-based Architecture, Machin-Learning Algorithms, Interoperability, Containerization, Clinical Data, CDMS, eCRF.

1. Introduction

Adaptive clinical trials incorporate multiple comparisons in the context of a disease or treatment. Changes are performed during the conduct of the trial in response to patient information accumulating and adaptive elements using pre-defined interim analyses [1]. In some platform trials, treatment assignments are based on the patients' biomarker profiles and precision health methods are incorporated into the interim and final analyses. Changes may need to integrate new biomarkers modifying the randomization process. Such changes should not impact the clinical study infrastructure or the clinical trial operation. With the emergence of AI-based biomarkers, biomarker stratification at the point of care is technically especially challenging. In the next section, we briefly describe the technical architecture solution used to integrate predictive algorithms and randomization application of the adaptive RECORDS-Trial.

2. Microservices-based architecture to support REDCORDS-Trial.

The Adaptive Clinical-Trial RECORDS (Rapid rEcognition of CS sensitive or resistant Sepsis) [2], needs robust, flexible, and interoperable technical architecture to integrate machine-learning algorithms developed by RECORDS project partners (i.e Versailles University, Berkeley University) to run AI-based biomarker stratification [2]. The trained algorithms are used to automatically predict features starting from dataset entered in inclusion form within the eCRF application. Predicted features are essential to

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determine patient the treatment options for specific patients, during the conduct of RECORDS-Trail.

To enable the adaptive RECORDS-Trial to use trained predictive algorithms, the Data and Innovation department has set up a microservices-based, extensible, and interoperable technical architecture. Each machine-learning algorithm, developed by RECORDS project partners, is wrapped by web framework to be used as a web service (WS). For instance, Flask framework has been used to wrap algorithms developed using Python Programming Language, and Plumber framework has been used to wrap algorithms developed using R Language. The web-based algorithms then have been containerized using Docker technology. On the other hand, the eCRF application used by adaptive RECORDS-Trial has integrated the WS related to the predictive algorithms in order to be called at each patient inclusion in RECORDS Interventional Study.

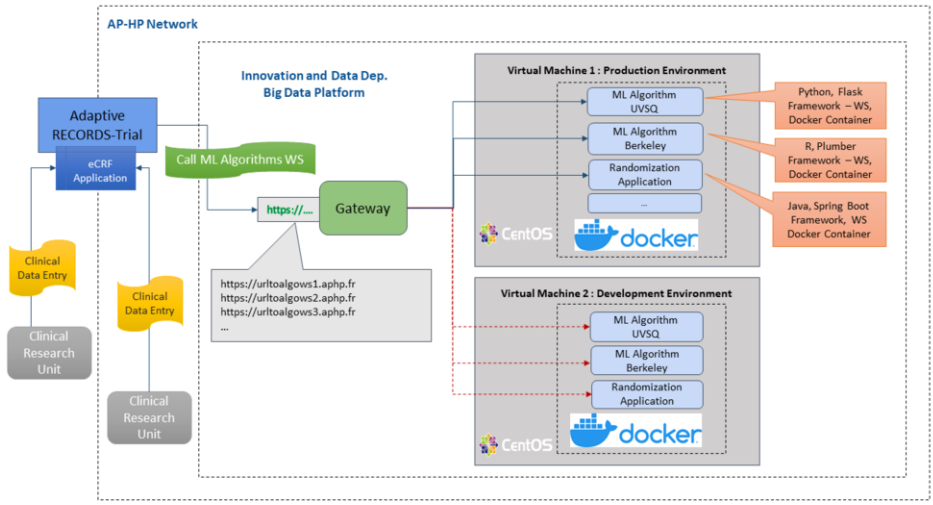

Figure 1. Global overview of the Microservices-based architecture to support the adaptive RECORDS-Trial

CDMS that integrates API (Application Programming Interface) can effectively interact with microservices and exchange data needed by adaptive clinical trial. The schema above shows an overview of the microservices-based architecture currently used to support the adaptive RECORDS-Trial. Open Source technologies like CentOS Operating System, Docker Engine, and Docker-Compose, are used to create the microservices architecture. To secure the microservices, all data streams are encrypted using a security certificate. In addition, HTTPS protocol is used to query the WS, as well as, all data flows pass by a gateway that uses additional security components such as Nginx Revers Proxy.

References

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