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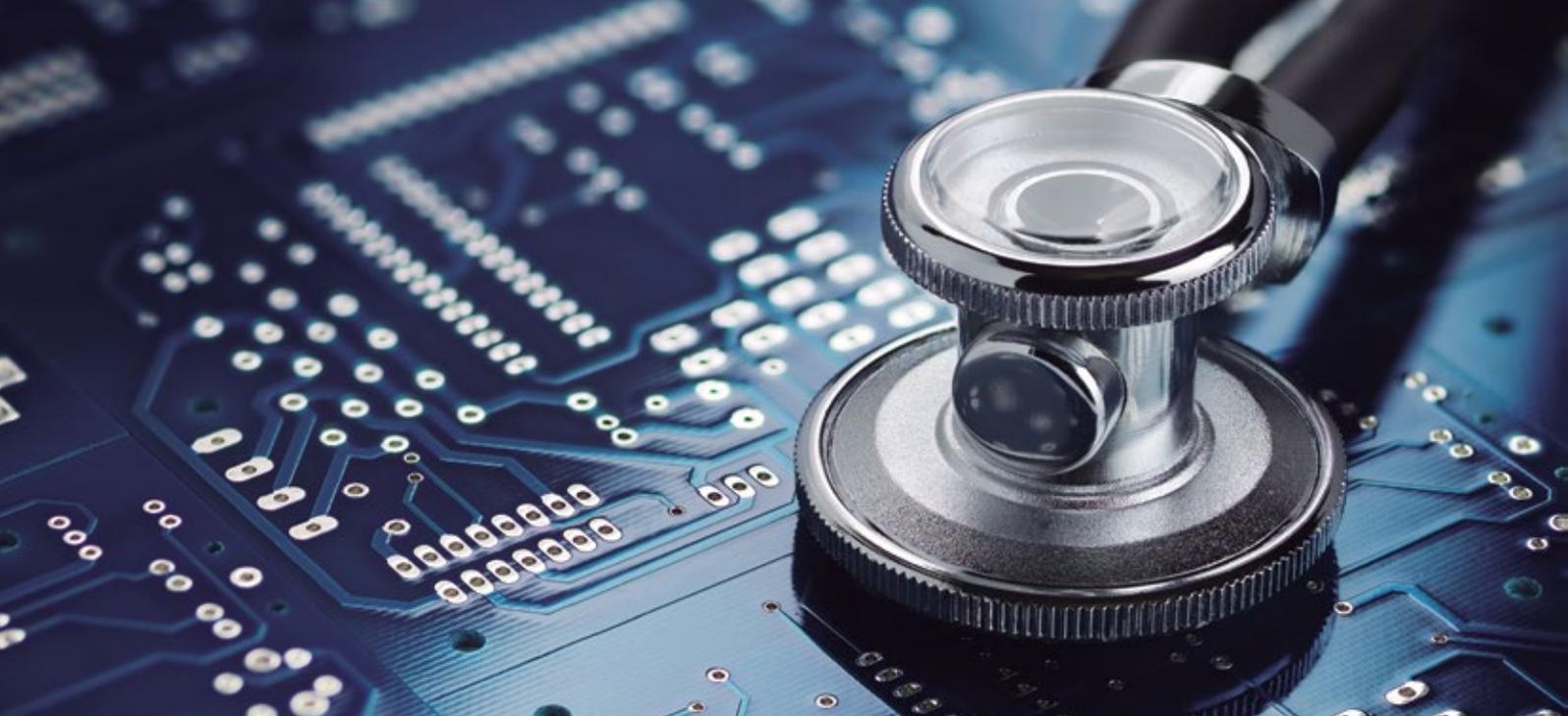
ANTI MICRO BIALS

USE (AND ABUSE) OF ANTIBIOTICS

**NEW THERAPEUTIC PROPOSALS IN THE FIGHT
AGAINST ANTIBIOTIC RESISTANCE**

MEDTECH AND WEARABLES

ANTIBIOTICS AND EDUCATION



AN ELECTRONIC DATA MODEL FOR A MORE EFFICIENT HEALTH SYSTEM IN LATIN AMERICA

By Daniel Gutierrez, Customer Solutions Director, Clinerion.

Access to electronic health data has never been so crucial both for Latin American healthcare systems as well as for its economies, as evidenced right now during the time of COVID-19. We outline the issues and challenges encouraging digitalization and the benefits it can bring, in particular, for accelerating recruitment for clinical trials, and tracking epidemiology of diseases within and across regions and populations.

Introduction: Digitalization in Latin America

The adoption of electronic medical records in health systems across Latin America has been an ongoing effort. The HIMSS EMRAM classification of the degree of hospital digitalization lists 31 hospitals in Latin America in EMRAM Stages 6 and 7 (highest degree of digitalization), of which 27 are in Brazil. ⁽¹⁾ By contrast, there are over 2000 in the USA and just under 3000

worldwide. There is still a ways to go for Latin America. A report from the Pan American Health Organization (PAHO) analyzing the state of electronic medical records (EMR) in Latin America and the Caribbean ⁽²⁾ highlighted up to thirteen benefits to the wide adoption of EMR, including the sharing of clinical information across entities, improvement of healthcare decision-making by tracking patient indicators in real-time, and acceleration of medical consulting.

1. HIMSS Latin America, *EMR Adoption Model*. Available at: <http://www.himssla.org/ehome/168684/emram>

2. Pan American Health Organization, *Electronic Medical Records in Latin America and the Caribbean: An Analysis of the current situation and recommendations for the Region*. 2016, ISBN 978-92-75-11882-5. Available at: <https://iris.paho.org/handle/10665.2/28210>

Foremost among these was that “the assistance of adequate technology may guarantee accurate identification of patients.”⁽²⁾ While the intention of this statement was probably broad, and could encapsulate, for example, precision medicine approaches, I would highlight one use-case, in particular, which is relevant for us in clinical research: the use of EMR to seek and identify suitable patients for clinical trial recruitment.

When it comes to running clinical trials, Latin America as a whole does not punch in its weight class. With a population of 418 million people⁽³⁾, the region is home to 5.7% of the world’s population, yet only runs 3.5% of the currently open trials on clinicaltrials.gov (data from July 2017)^(4, 5). The region has large, urban populations of patients, who are still drug-naïve; and it has highly involved and experienced investigators⁽⁶⁾ and good healthcare systems (with 16,000 hospitals⁽⁷⁾). Why then are clinical trials lagging?

Challenges include the lengthy approvals processes in the region, with fragmented procedures for drug registration. Additionally, the lack of awareness, advance expertise and infrastructure on all fronts of patients, physicians and hospitals respectively, lead to low patient acceptance when being recruited for trials and insufficient number of investigators in the region to satisfy demand. The third problem is that of low level of investment in Latin America in development and research compared to other developed countries, leading to a lack of resources, supplies and technologies for diagnosis and treatment^(5, 8).

A second key stated benefit of the PAHO report was – presciently! – EMR facilitation of epidemiological surveillance. In the new age of COVID-19, there is a great need for a global perspective to healthcare data and an understanding of disease incidence and transmittance, patient cohorts, treatment paradigms, and patient outcomes beyond borders or time zones. Accessing patient data is a crucial approach for countries and cities to monitor evolutions of pandemics and prepare ahead. This is true not only for COVID-19, but also for any other mass population disease such as diabetes, or heart disease, that will also affect a region like Latin America, economically.

Additionally, from a patient-centricity point of view, it should be mentioned that a 2013 paper analyzed the correlation between the degree of digitization of a hospital and a patient’s experience of care, and found that hospitals with exceptional levels of digitization (EMRAM Stage 7) showed significantly higher care scores.⁽⁹⁾

3. United Nations, Department of Economic and Social Affairs, Population Division. *World Population Prospects: The 2015 Revision*
4. clinicaltrials.gov

5. Magalhaes L, Chin LV, *Accelerating Clinical Research in Brazil*, *Journal for Clinical Studies*, Volume 9 Issue 4, 2017.

6. Silvia Bendiner, Fernando Ferrer, *Pharma Strategies in Latin America Keys to Success*, *Mapi*, March 15, 2016

7. Guillaume Corpart, *Latin America: ripe potential for pharma*, *Pharmaphorum*, May 15, 2015

8. Christian Rolfo, Christian Caglevic, Denisse Bretel, David Hong, Luis E Raez, Andres F Cardona, Ana B Oton, Henry Gomez, Urania Dafni, Carlos Vallejos, Christoph Zielinski, *Cancer clinical research in Latin America: current situation and opportunities. Expert opinion from the first ESMO workshop on clinical trials*, Lima, 2015, *ESMO Open* 2016; 1(4): e000055, 2016 Jun 17

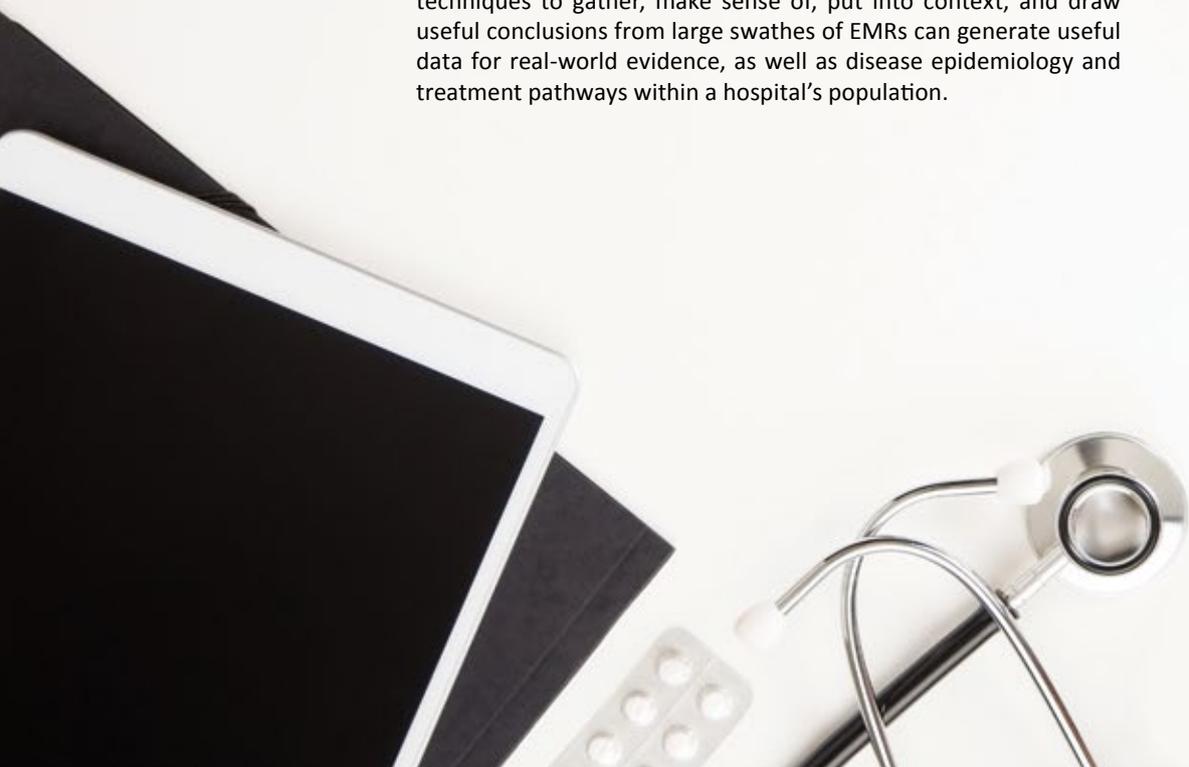
9. Jarvis B et al, *Assessing the impact of electronic health records as an enabler of hospital quality and patient satisfaction*, *Acad Med* 88(10): pp1,471-7, 2013

Technology solution: an EMR-based system querying live patient data across silos

What we require is a system which has permission to send queries to multiple hospital patient EMR systems in real-time, and collect and aggregate the results. This can support the entire process of drug development and launch with real patient data, from clustering disease incidence, to identifying patient clusters for testing, to gathering real-world evidence, to tracking patient outcomes.

With EMR-based patient recruitment, electronically sending a protocol in the form of a query to multiple sites enables trial sponsors to evaluate numbers of patients fitting a protocol's complex criteria across all linked sites, nearly instantaneously, and identifying the hospitals with the highest numbers of eligible patients for setting up a trial site. This effectively pre-screens the patients and removes the subjective element from the process. Depending on how they are configured, electronic patient recruitment systems may screen for patients on a continuous basis and identify eligible patients in near real time. This offers important advantages where trials are time-sensitive, or for capturing eligible candidates directly when they enter an emergency room.

From an epidemiological standpoint, using Big Data analytics techniques to gather, make sense of, put into context, and draw useful conclusions from large swathes of EMRs can generate useful data for real-world evidence, as well as disease epidemiology and treatment pathways within a hospital's population.



Patient Network Explorer

At Clinerion, we propose a hybrid platform of federated local installations at hospitals and a secure private cloud, which distributes the queries to the federated nodes at the hospitals and receives results from them. Data is rendered interoperable as a result of ontology- and dictionary-mapping performed during installation. Patient data privacy is assured by ensuring that patient data is anonymized at source and that identifiable data is never removed from the hospital at any point.

Clinerion's platform, the Patient Network Explorer, currently covers 32.9 million patients in 72 healthcare organizations, in 16 countries around the world, with a further 11 countries contracted.

In Latin America, 13 hospitals, nationwide in Brazil, have joined Clinerion's Patient Network Explorer. Using Patient Network Explorer,

these hospitals can share their patient data with pharma sponsors for search and identification of available patient cohorts, allowing the pharmaceutical industry to directly engage in patient pre-screening, site selection and feasibility (this assumes they have patient consent and ethics committee approvals).

In the Spanish-speaking Latin American countries I'd like to mention the Pablo Tobón Uribe Hospital (PTU), in Medellín, Colombia, which is about to kick off their installation of Patient Network Explorer. By the beginning of the 2021, Pablo Tobón Uribe will be the first hospital in Spanish-speaking Latin America that can be queried from Clinerion's online dashboard, paving the way for other hospitals to embrace a new technology that will transform the way clinical trials are run. The impact will not just be local, but global: not only will it be possible for Colombian CROs and local affiliates of international companies

to query Colombian clinical data through the Clinerion platform for the first time; but since Clinerion has a global reach, it will also allow international pharma companies and the world-wide CRO industry to query and pre-screen Colombian patients, longitudinally and with incredible resolution.

The technology doesn't only support pharma and CROs. Hospitals that implement Clinerion also gain access to Patient Network Explorer's Patient Finder module that allows the site to search through all the patient base medical information in their EMR system, including historical records of past patients. Patient Finder provides a gateway for the hospital to onboard incoming trials, or to begin site-initiated trials. Additionally, via Patient Finder, the site can preview the performance data of their own hospital. The latter includes performance data on current ongoing trials, clinical researchers and site expertise, amongst others.



Technology Trends: What's Next?

A trend that has started amongst hospitals in the Clinerion network, in relationship to Patient Finder and Patient Network Explorer, is to participate in research collaboration with other local hospitals. This allows teams to gain complementary expertise by connecting with other researchers and Principal Investigators and most importantly to increase the available patient data. This therefore offers benefits not just to epidemiology and outcomes studies, but again also improving clinical trial recruitment success rates by expanding the pool of patients. 80% of clinical trials are delayed, often for recruitment-related reasons.⁽¹⁰⁾

The hybrid cloud/federated installation technology proposed above can also be implemented in such closed networks. In Switzerland, Clinerion was responsible for the implement of a benchmark project for remote patient data access among hospitals. This was the Swiss Personalized Health Network (SPHN), which is a national and cantonal effort between public university hospitals such as Universitätspital Zurich, CHUV (Geneva), Inselspital (Bern) and others, that enables the country to democratize access to clinical data between the university hospitals and enhance research and the

collective expertise.⁽¹¹⁾ Outside Switzerland, Clinerion has already received interest from Brazilian hospitals for the same concept.

Image data has also recently found interest in the pharma industry for clinical research. The goal is to use clinical images in the definition of patient cohorts during the preparation for clinical trials, understand disease aetiology and anticipate the response to new molecules. For the latter point, clinical images additionally provide information about previous therapy administration schedules (begin date, end date, dose history and combo therapies), TNM tumor classification status and provide a baseline necessary in efficacy studies. Clinerion and some of its 72 online hospitals are exploring avenues to enable the pharma industry access EMR + images together.

Digitalization of hospitals brings many advances in patient care and drug development. As hospitals in Latin America evolve by digitalizing patient electronic health records, they will gain advantages in supporting their research and clinical trials. The take home message is that the future in clinical trials for Latin America looks promising and with huge potential, however the time to act and get ready is now.

10. Earls E, *Clinical Trial Delays: America's Patient Recruitment Dilemma*, 2012. Available at www.clinicaltrialsarena.com/features/featureclinical-trial-patient-recruitment/

11. Visit: www.sphn.ch.



Daniel Gutierrez

Daniel Gutierrez is a physicist and cardiac physiologist by training, educated at the Colombia Universidad del Valle as well as at the EPFL (Lausanne), University of Bern, and ETH Zurich. Specifically in the latter, Daniel expanded his knowledge in biomedical engineering and molecular imaging applied to pre-clinical drug development in the field of oncology. Daniel additionally applied and furthered his experience in immuno-oncology and therapeutic antibodies while working at Roche where he was key

in the development of techniques to visualize and understand the mode of action mechanisms of antibodies when killing tumours, using the drugs Gazyva, GA201, as well as other T-cell bispecific antibodies.

Later, Daniel founded his own company, GeneLook AG, where he developed and implemented a digital health solution in the field of genetics to remotely pre-screen and validate rare disease patients that were potentially enrollable in clinical trials. He developed a platform to enable patients share specific mutations both found in their DNA and involved with their diseases, while keeping the rest of their DNA code undisclosed.

In early 2020 Daniel joined Clinerion Ltd in Basel where he is implementing new business models and working in the field of patient pre-screening and RWD/RWE access. At Clinerion he is applying his knowledge to enable the pharma industry to identify sites of interest and consequently allow patients expedite their access to best in class molecules.