Emerging Treatments
For Spinal Cord Damage

The Biggest Regulatory Moments of 2019
And How They'll Impact 2020

Rescue Trials
When Should You Call for Help?

Unified Trial Governance
Why CTMS is the Jewel in the Crown

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Our healthcare is becoming increasingly interconnected as technologies allow us to be more connected to our devices, to other people and healthcare services and providers. Our healthcare footprint is now part of our digital footprint. Our digital footprint is now part of a larger digital ecosystem that promises to enable better patient care through better insights. The challenge is to enable while also maintaining individual privacy and data security. Increasingly, there are standards to enable better integration, better data integration and better data security. The patient journey is now enabled through the EMR data allowing patients and doctors to be connected, live-streaming across time, geography, condition and treatment through direct patient-centricity.

**The Healthcare and Life Sciences Mission**

- Improving patient care and outcomes should be the overarching goal of any technology and digital engagement in healthcare and life sciences.
- The common goal of improving patient care and outcomes is a unifying theme that connects life science research and therapeutic development with direct patient care, treatment as well as care value and reimbursement.
- Digital capabilities represent significant enablement throughout the life science and healthcare ecosystem toward better therapeutic discovery, development, patient treatment, experience and journey as well as outcomes including both healthcare metrics and cost.

**Introduction**

“Digital Healthcare” has become a recent buzzword representing the application of digital or data technologies to healthcare, from patient engagement to apps and digital media, from connected medical devices and biomarker metrics through to IoT (Internet of Things), from patient data and insights to digital records.

Electronic health records (EHRs) or electronic medical records (EMRs) are the key capture and integration layer for digital patient data and represent documented data of the patient’s journey through healthcare, from diagnosis, to treatment, to outcome.

At the same time, EHRs/EMRs are currently limited to clinical case data only and contain both structured and unstructured data.

Increasingly, the demand from digital healthcare is for more structured data and more granular patient detail, including genetic test results or other ongoing values such as EKG, hypertension metrics or blood sugar levels that may not be structured or captured between clinical appointments.

As an additional concern, while there is more demand for data, there is greater sensitivity to patient privacy, security and higher thresholds to ensure data compliance in GDPR, HIPAA and the new CCPA (California Consumer Privacy Act) legislation.

**The Patient Digital Journey**

Increasingly, patients are looking for closer engagement in their own treatment and responding favourably to the use of smart devices and other technologies they are familiar with to understand and manage their own care. At the same time, pharmaceutical companies want to better understand and identify patients where the treatment can be most efficacious as well as be able to track outcomes and mitigating factors. Care providers want to improve patient outcomes and reduce re-occurrence and readmission risks that affect their reimbursement bottom line.

From a patient perspective, the patient-centric message must be that we are focused on treating you, the patient, not just the disease. Traditionally, pharmaceutical companies and treatment providers grouped patients and treated them as broad categories, not as individuals. If you are a breast cancer patient, traditionally your treatment would be the same, within parameters (size, hormone-responsive or not, peripheral migration or not), as for any other breast cancer patient with the same metrics. This is changing with personalised health care and precision medicine, and with things such as companion diagnostics and other genetic technologies that enable improvements in an individual patient’s diagnosis and definition of the best course of treatment.

As treatments become more individualised, patients expect and want an individualised experience. The power of digital technologies/data connectivity is to change the patient’s perception from not just being a category but into having an individual experience and engagement with their treatment, even if the back-end platform (or handheld device) is the same. Allowing the patient to create their own engagement has been shown to be extremely effective as in chronic disease management such as diabetes, addiction and neurology.

The future of medicine is about the patient’s individual journey and staying connected, engaged and in control, each step, and one day at a time.

**The Digital Data Problem Relative to Healthcare**

The amount of data and relevance of data to patient healthcare and improving care metrics is exploding. The main challenges are data relevance to patient care, quality and interoperability. What data is important to treating patients, how is it important, how should it be structured, shared and prioritised? One effort to meet these challenges is FAIR, a data modeling standard, that posits the principles that data should be (F)indable, (A)ccessible, (I)nteroperable and (R)eusable by both humans and machines. The challenges of big data are the 4 Vs: volume, velocity, variety and veracity – and healthcare data is no exception.

As mentioned, EMR data is the electronic clinical record of a patient’s journey from condition to diagnosis and treatment. The data is as multi-dimensional as the patient’s interactions throughout their healthcare system. Structured information elements, including demographics, diagnoses, procedures, medications and laboratory tests, tell the chronology of the patient journey. EMR data also includes unstructured data elements such
as medical images, EKGs, genetic test results and physician notes (including pathology reports and discharge reports) that cannot readily be queried but are extremely relevant to patient condition and care metrics. The goal is “meaningful use”, i.e. that electronic exchange of health information should enable improvements in quality of care. The concept of meaningful use rests on five pillars of health outcomes policy priorities: 1. Improve quality, safety and efficiency, and reduce health disparities 2. Engage patients and families in their health 3. Improve care coordination 4. Improve population and public health 5. Ensure adequate privacy and security protection for personal health information

The additional challenge is data privacy and ownership. Who owns a patient’s data if not the patient? How can a patient’s data be collected and shared within their healthcare network and with their attending physicians to guide and facilitate the patient’s care while also protecting personal and private information and conforming to new healthcare data regulations? There are several new business ventures and cooperatives around healthcare data exchanges, where the patient owns their own healthcare, lifestyle and environmental data, and can embellish and selectively share it. The bet is that patients will have increasingly more access to and control of their own personal healthcare data.

Collaboration

Patient healthcare is increasingly a collaborative process between different healthcare services, both inpatient and outpatient care, different physician specialties, care centres and testing services which are no longer exclusively managed through a single point of contact (traditionally, the family or primary care physician). Increasingly, with the advent of greater patient travel capability and telemedicine services into rural areas, it is not uncommon for patients to be seen in different care settings and in different contexts and as they search out different specialty care options. From a healthcare perspective and with the purpose of treating patients with more context to their entire journey, there are numerous efforts between hospitals, within systems and across systems, to be able to share patient data in order that redundant procedures and treatments, and perhaps even misdiagnoses, are prevented. In Massachusetts, the Massachusetts Health Information Highway (MASS HIWAY) is a secure statewide network that facilitates the transmission of healthcare data and health information among providers, hospitals, and other healthcare entities as allowed by applicable state and federal laws.

In New York City, in the EPIC Together Program, several hospitals are combining efforts using EPIC’s cloud-based EMR system to combine inpatient and outpatient charts, as well as allow patients to share their records with other institutions. More broadly, the eHealth Exchange (formerly the NHIN) is seeking to bring all US data together.

In Switzerland, where the writer is based, the SPHN (Swiss Personalized Health Network) has several initiatives to enable teaching hospitals to share data and understand care metrics across the country. Most recently, the partnership in the US between Google and the medical system, Ascension, to store and analyse the data of millions of patients, could have huge reach. Ascension operates 150 hospitals in 20 states and the District of Columbia. Under the arrangement, the data of all Ascension patients could eventually be uploaded to Google’s cloud computing platform. In Korea, the Korea University Medical Center is leading national efforts to enable big data analysis of patient outcomes and support the development of personalised medicine and artificial intelligence in healthcare by sharing data across sites in a cloud-based, Blockchain-protected system, the Precision-Hospital Information System (P-HIS).

Back in Europe, the HONEUR collaboration has the goal of accelerating the development of new cancer treatments and the improvement of patient outcomes by bringing together data from multiform institutions across the continent that have large data sets of patients diagnosed with haematological malignancies. And in the Netherlands, where there is an average of 43 isolated medical records per person, the Connect2health consumer programme is just being launched to unify the data under one data model, to ease reuse of data and the personalisation of health advice and interventions.

The point of all of this is that healthcare has become collaborative and there is no longer a single point of care for most patients. Data integration is critical to improving patient care and outcomes from the levels of their existing care, but standards of data integration, interoperability, data security and standards for data anonymisation from personal and private patient data are critical for success.

Data Standards

Data standards have become as critical as the access to the data itself. Much like the diplomatic courtier language of the Middle Ages, what should the “lingua franca” be in the realms of healthcare data and patient records? How can disparate systems create an overall patient journey profile?

There are several data standards. SDTM is used for submission of clinical data to the FDA. HL-7’s FHIR provides guidelines and standards for data exchange. OHDSI & EHDEN’s OMOP brings observational data into the mix. OHDSI is a community effort to standardise healthcare data into a common data model and vernacular called OMOP. The OMOP common data model (CDM) is designed for EMR data as well as administrative insurance claims data, allowing users to generate insights from a wide variety of data sources, both within and outside the United States. The intent is that once data sources have been converted to the OMOP CDM format, that several open source analytical tools are available to generate standardised queries and insights.

What does this translate into for patients and actual patient care? A common data model and vernacular means that regardless of when and where a patient is seen and for whatever test, treatment or diagnosis, that the patient’s records and charts can be viewed and made available in totality in one context, and not as disparate or fragmented clinical records and insurance claims.

Although OMOP currently works with structured EMR data, there are numerous efforts to also extend this to unstructured EMR data using natural language processing (NLP), a form of AI. The intent is enabling queries across structured and unstructured data that enable better patient-centricity, stratification, care metrics and patient models such as relevant cohorts.

The Healthcare Network

Healthcare is changing; it is becoming multi-dimensional through greater connectivity between patients and care-givers and enabling digital technologies. Patient metrics are no longer limited to individual clinical settings and doctor’s visits but can now be facilitated through IoT technologies that enable metrics
recording for virtual clinical trials as well as apps and messaging that engage the patient between doctor visits.

Healthcare is now delivered through a network of care-givers and services. At the same time, patients and their data are also part of their own patient network: the ecosystem of patients and their data represented within a healthcare system, hospital network, primary care consortium, or combination of any of these across country and geographic areas. The power of these networks to improve patient care is immense. Not only can individual patients be cared for holistically through the entirety of their digital experience, but a better understanding of care metrics, care efficacy as well as epidemiology can be derived by looking at care within and across different settings.

“Value for care” is now the mantra in healthcare: to be able to demonstrate treatment and therapeutic effectiveness. Patient networks are critical to being able to trace a patient’s treatment and outcomes and to examining the effectiveness of therapeutics in different settings and as part of different treatment regimens.

A patient’s journey is not alone but part of thousands, if not millions, of steps by other patients also on their own paths. We learn from each other and enable better outcomes, as although we are each an N of 1, we have, in aggregate, the ability to better understand disease, develop treatment options and better deliver individualised patient care. It all arises from being able to predict a patient’s journey by having access to models based upon longitudinal data, “Precisely practicing medicine with a trillion points of data,” as evoked by Dr. Atul Butte of Stanford University.16

Clinical Trials, Integrated Research Partnerships and Real-world Data
The merger of digital healthcare and patient data networks has also increased partnership and synergy in a number of areas of patient care, but in clinical trials, especially between sponsors and CROs to better identify patients and accurately recruit patients specific to the clinical research and study design.17 As EMR data is the most accurate resource of clinical patient data, access to patient networks of EMR data is critical to clinical research. Not only is EMR data critical for understanding where actual patients are, but also for effective study design and site selection. The anonymised data is also invaluable for retrospective studies, studying treatment regimens and developing surrogate cohorts. EMR data is a highly accurate source for RWD18 to understand trends and care and differences geographically and within care centres.

Below, we outline cases for both areas.

Use Case: EMR data for Patient Identification for Clinical Trials and Clinical Research
Keyla Deucher, Managing Director of BIOSERV SMO, has run recruitment for trials at the Hospital São Vicente de Paulo, Brazil. The results19 show that the use of the EMR-data-driven solution:

- Allows trial staff to spend more time on patient outreach and screening. (Figure 1)
- Finds patients not otherwise findable. (Figure 2)

“Screening Timeline”

Screening Timeline

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Figure 1: EMR patient network can be used to more rapidly identify potential patients than traditional outreach methods, allowing more time for extra outreach and patient validation.

![EMR patient network](image)

**Of the total patients found, 24% were findable by data-driven solution.**

**Of the total patients found, 71% were only accessible by that data-driven solution, while 29% could be found by both methods.**

**Average:**

- Recruitment Source by Therapeutic Area

*Figure 2: Total patients found by EMR-data-driven solution was significant in many therapeutic areas where relevant data is digital, and many patients are only identifiable by the digital method in comparison to traditional outreach methods.*

Use Case: Real-world Data Performance Insights
Use of an EMR-based solution offers a combination of multi-dimensional query definition, real-time search across multiple networked electronic health record systems made interoperable by the use of semantic and ontology methods, and a highly scalable hybrid cloud- and federated local installation-based platform. Users can thereby identify relevant anonymised patient data for a given protocol through automated screening of EMRs, using real-time data. This enables optimisation of study protocols, more efficient site selection and faster patient search as well as anonymised RWD collection options. This can bring the following applications and use cases:

- Synthetic control arms: using longitudinal data to create virtual control groups is helping reduce clinical trial enrolment, cost and needless duplication of patient treatment groups for which treatment data already exist. Additionally, using EMR data to develop and test synthetic cohort models is critical to epidemiology and disease progression modelling.
- Predictive modelling: data scientists can use the time series information to predict the number of new patients for a specific indication in the future. Those predictions could help in clinical trials to model incidence/prevalence of specific condition of interest for a site.
- Therapeutic insights: health researchers can show insights into frequency and volume of use of medications and procedures and changes therein over time. They can also monitor from which date new medications/procedures get prescribed to patients — and if new prescriptions decrease the usage of other medications/procedures.
- Healthcare market insights: create market segmentation reports, e.g. monitoring the frequency and volume of prescriptions for medication across pharmaceutical companies.
- Compound-specific usage statistics:

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- Healthcare market insights: create market segmentation reports, e.g. monitoring the frequency and volume of prescriptions for medication across pharmaceutical companies.
- Compound-specific usage statistics:
Anonymised EMR data can be used for longitudinal retrospective studies based upon various cohorts such as disease diagnosis and treatments. As an example, multiple myeloma patients diagnosed in 2018, as found by searching patient EMRs on Clinerion’s Patient Network Explorer, could be analysed to show demographics, Charlson comorbidity risk scores21 and Bortezomib treatment regimens. (Figure 3).

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