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EMA adopts new Telematics Roadmap

The European Medicines Agency adopted its 'EU Telematics Strategy and Implementation Roadmap 2015 - 2017' on 6 August, which sets out a 'high-level' plan for the delivery of IT solutions arising from European pharmaceutical legislation and policy.

Brian Kelly, Associate at Covington & Burling explains that the Roadmap contains features that may be helpful to the development of eHealth in the EU, such as improvements to EudraVigilance and mandating the use of a streamlined Periodic Safety Update Report. "The envisaged EU Medicines Web portal may also be a useful, publically accessible information resource," adds Kelly. "Many of the centralising measures contained within the Roadmap, particularly in the field of data integration, will lead to greater data exchange and broader public health benefits."

The Roadmap includes a programme for the development of solutions to support the implementation of the Clinical Trials Regulation and a detailed table outlining the business impact of the Roadmap to help companies prepare for the changes.

IN THIS ISSUE

Online Pharmacies DocMorris in the EU **03**
Health Data US **05**
Korea Data breach **08**
Cyber Security FDA medical device alert **09**
Denmark Development of eHealth services **11**
Belgium Open Data **13**
Data Breach Before and after a breach **14**
Investment EU **16**

UK extension to EHR access plans raise security concerns

The UK's Health Secretary Jeremy Hunt announced on 2 September plans to enable patients in England to access their full GP record online within the next year, including information such as blood test results, and to be able to view online information from all their health and care interactions by 2018. Hunt also expressed his vision that by the next financial year 15% of NHS patients will access NHS records and services on smartphones.

"A smartphone is simply one of a number of devices that will provide the means of access to data," explains Matthew Godfrey-Faussett, Partner at Pinsent Masons LLP. "With the extension of remote access come the key issues of how to ensure data security and avoid data misuse." Robin Smith, Health 2.0 Futurist, expresses concern, noting that "unless there is a quantum leap in the encryption technology possible for handheld devices then they will become easy prey for cyber criminals."

To address concerns around the confidentiality of medical information, Hunt has outlined a number of measures, including a review of standards for patients' confidential data by the Care Quality Commission and the development of personal data protection guidelines for organisations by Dame Fiona Caldicott, the National Data Guardian for health and care. "The all important element of trust, that is vital in any data sharing arrangement, has been lost," said Godfrey-Faussett. "The first step in rebuilding that trust will be the issue of the new Caldicott Guidelines. Once finalised and implemented, the resulting framework should allow the creation of consistent best practice and go some way to reassuring professional and patient bodies."

Tim Kelsey, NHS England's National Director for Patients and Information, has separately announced measures to encourage healthcare providers to become paperless at point of care by 2020. These include a requirement for providers to submit a plan - a digital roadmap - explaining how they will achieve this paperless target. "The NHS is under massive strain in terms of limited financial resources, over-worked staffing and change projects that continue to dog genuine efforts to deliver world class services," said Smith. "There should be a commitment to digital services and 2020 should be targeted as a reasonable mid-term point for transformation. However unless there is an increase in innovation funding this might be an optimistic deadline."

FDA to launch cloud-based genomic sequencing platform

The US FDA announced the launch of a new crowd-sourced, cloud-based platform, precisionFDA, on 5 August, which aims to enable developers of genomic sequencing diagnostics to share data, test methodologies and develop standards.

The FDA is developing new regulatory strategies for next generation sequencing ('NGS') based clinical tests as part of the Precision Medicine Initiative ('PMI'), which aims to transform US healthcare by tailoring medical treatment and prevention to an individual's unique characteristics.

"The precisionFDA initiative furthers the PMI goal to promote the sharing of genomic data and the FDA's interest in ensuring consumer safety by providing a mechanism to improve the accuracy and validity of NGS tests," said Barbara Cammarata, Counsel at Sidley Austin LLP. "It may also play a role in the regulation of Laboratory Developed Tests ('LDTs') many of which rely on NGS technology."

The FDA announced on 8 September that it will be holding two public workshops in November aimed at 'taking genomic testing to the next level,' which will focus on performance evaluation standards and the challenges in clinical validation of NGS tests.

"Many stakeholders view the FDA's work in this area with conservative optimism: if the agency seeks to over-regulate, as many believe they did with LDTs, there will be uproar," adds Cybil Roehrenbeck, Counsel at Kilpatrick Townsend & Stockton LLP.