Collaborative cloud-based solutions in Africa

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1 October 2019

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
A new radical platform that redefines the way pharmaceutical companies share data with regulators.

It represents an innovative approach to facilitate collaboration across agencies using artificial intelligence, machine learning, and predictive analytic techniques in a modern cloud-based architecture.
Current process for regulatory filings

- **Multiple databases**: at the MAH level and at agency level
- Sponsoring company sends information to regulatory authority in discrete packets
- Global registration requires multiple (often repetitive) filings
- Multiple sponsors may provide relevant information, but data silos can create a barrier to sharing internally
- Regulators can share learnings and (some) information through designated programs
Alternative, preferred submission

Data is captured and stored directly from the source to the cloud.

Data is screened and evaluated by technology according to pre-agreed criteria with the Agency (i.e., design space).

Data not in line with predicted path

Data in line with predicted path

Sponsor to re-engage with Agency

Secured by Blockchain

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Cloud-based process for regulatory filings

- **PAPERLESS**: MAH data curated and stored in the “cloud” (a company/shared/third-party controlled data platform)
- **REAL-TIME**: Regulatory Authority receives data access as soon as the regulatory dossier is submitted
- **AVAILABLE**: Regulatory Authority data analysis can take place remotely at any period on data-housing platform
- **COLLABORATIVE**: Approach permits simultaneous review by multiple regulatory authorities and allows input from multiple other sources to guide regulatory decision making
- **TRANSVERSAL**: Approach also allows regulators to draw insight from related submissions (with proper permissions)
- **INNOVATIVE**: Enhances the ability of sponsors and regulators to use and integrate new sources of data, e.g. Real World Data

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Adopting a **cloud-based solution** can:

- In the context of the Africa Medicines Agency: *“leapfrog” towards a seamless regulatory future*
- **Achieve regulatory alignment** in terms of framework and methods – given the shared platform
- **Reduce country-specific requirements**
- **Share information and good practices** on lifecycle management of medical products
- **Be the model continent** that pioneers innovative science-based regulatory approaches
Thank you!