HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

UNICOM WP4

HPRA IDMP Implementation - Lessons Learned

21st June 2022

Agenda

- About the HPRA
- Objectives & Scope of Work
- Project Areas of Focus & Lessons Learned
- National, Network, Strategic Learnings
- Future Activities
- Concluding Points

About the Health Products Regulatory Authority

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

- Responsible for regulation of:
  - Human and veterinary medicines
  - Medical devices
  - Cosmetics, blood, tissues and organs
- Compliance and enforcement
- 380 staff, interim hybrid working arrangements
- Organisation Strategic Goals (2021-2025)
  - Health system partnerships
  - Progressive regulation
  - Communication and engagement
  - Enabling innovation
  - Great people, great processes
- Primary enterprise system "Eolas" (human and veterinary medicines); number of legacy platforms being consolidated on to Eolas. Objective is to create a single application platform and data repository

Objective & Scope of Work

- WP4 Objectives
  - Progress towards providing ISO IDMP compatible IT systems
  - Progress legacy data migration towards ISO IDMP standards
  - Progress data connectivity to EMA's SPOR services
  - Provide a prototype of an ISO IDMP compatible data feed to national eHealth providers
  - Increase knowledge and share best practices of how to implement ISO IDMP at NCA level
- HPRA Scope of Work
  - Analysis and amendment of business processes, refactoring of IT systems and interfaces
  - Transform data to align with ISO IDMP standards
  - Ensure data and data feeds to external stakeholders are ISO IDMP compliant
  - Utilise EMA's SPOR services as part of the data management process

Focus & Lessons Learned (Applications)

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

- Enterprise application (Eolas) was relatively new and design requirements for IDMP taken into account during build
- Initially assumption was that system was closely aligned with IDMP, with limited changes required
- Detailed analysis identified a number areas requiring rework
- Data quality issues (duplication) were identified due to limitations in the system design. In some cases the system design was overly complex while missing some essential elements
- Controls around master data creation required change as not all checks were in place to ensure ongoing data quality
- Redesign of screens to capture new information and improve workflow
- Using a shared platform required a ‘whole of organisation’ view, including functions to be onboarded in the future

Focus & Lessons Learned (Data)

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

- Data stored in various systems across the organisation – WP4 facilitated focus and a driver for consolidation to a single platform. Ongoing effort
- Technical Data Changes
  - Gap analysis between our existing data model and IDMP
  - Significant level of duplication of data identified. Mapping substances, referentials, and organisations to their corresponding SPOR IDs has doubled as a mechanism for identifying and archiving duplicates
  - Extensive business user input was required to 'enrich' our existing product data with the additional required information
- Data Cleansing and Management
  - Shared system for Human and Veterinary medicines; substances, referential, organisations, and product data from both domains co-exist within the same database. Case management system also feeds product data to the HPRA website
  - Required cross-functional collaboration when dealing with systems and data common across multiple regulatory functions
  - Established data stewardship roles and processes to control data quality, consistency and standardisation of data
  - Having clear owners from each department and communications channels in place was essential for timely decisions and ensuring that project work didn't unduly impact on operations
  - Assessment teams classified different types of data enrichment/cleansing work and assigned it to different skilled resources accordingly
- The quality and availability of the existing data will drive how much effort is required from business users
- Master data management and data governance principles required to ensure ongoing compliance

Focus & Lessons Learned (Resourcing)

- Profile of Project Resources:
  - Business Owner(s) familiar with the data and the regulatory requirements, empowered to make decisions regards data and systems requirements
  - Data Analysts familiar with existing systems/databases and data model, and familiar with IDMP
  - Developers with experience in data migration/integration projects, ideally familiar with the data model
  - Project Manager to co-ordinate activity
- Significant benefit from having these resources onboard and involved early in project life cycle
- The data analysts develop an understanding of complex data models, in house resources rather than external staff to avoid challenge and time required for resources to be productive, and retain knowledge
- Factor in on-boarding and familiarising time for external that resource with the business terminology, data, etc

Learnings (National)

- Greater process discipline required to maintain data quality, completeness and avoid duplication
- Extra effort required to improve and maintain data quality is not excessively time consuming
- Positive effect of having clean, correct data. Consistent data across functions, improvements in reporting, measurement and monitoring
- Improved focus on relevant data
- Importance of having data stewards providing a cross organisation perspective
- Anticipation of further improvements and benefits as DADI becomes available and use of SPOR data becomes mandatory
- Need to improve awareness and understanding within the organisation of the longer term strategic vision and pathway, and benefits to the overall health system

Learnings (Network)

- Importance of developing and communicating the target operating model and the long term product lifecycle management (processes, systems)
- Maintaining consistent data across the Network – data synchronisation, precedence, reconciliation rules
- Develop a Network approach to reduce duplication of effort required for integration at NCA level
- Simplified complexity of application integration (API). Facilitate easier integration through reduction in number of endpoints, in particular where common file structures are used

Learnings (Strategic)

- Consistent communication of a clear Network strategic vision to broad range of stakeholders, and the pathway to achievement
  - At the outset, limited understanding of the operational rationale for the time commitment and effort involved
  - Challenges because business users were being asked to contribute resource time to a project for which the benefits were distant
  - Some uncertainty around longer term benefits, current focus on compliance rather than efficiency
- Ultimate benefits also have dependencies on success of other Network projects e.g. DADI. Wider and consistent use of SPOR data will facilitate process benefits including automating case creation processes
- Continue to develop pathway to integrated regulated product lifecycle
- Broadening the vision into the wider health system

Future Activities

- Migrate other organisation functions and data repositories to single platform
- Continue to verify completeness of IDMP data sets and structure, continue to clean and check data, refine data quality metrics
- Establish a process and mechanism for ongoing synchronisation and alignment with SPOR
- Improve accessibility of data to national health system stakeholders
- Continue to develop organisation of Network product lifecycle strategy and changes
- Continue to develop the organisations understanding of the long term operating model

Concluding Points

- Although WP4 is a discrete work package, it is not a one off activity. Ongoing evolution in the regulatory system
- Closer integration across the Network and ultimately the health system
- Emphasised the need for NCA to remain / be engaged to understand and (influence) central and Network initiatives; NCAs participation and contribution is vital
- Prioritise and focus available resource pool

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thank you