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WP4 IDMP implementation at National Drug Agencies

D4.4: Germany: Progress report on implementation

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Main author(s):

Peter Bachmann	PB	BfArM

Other author(s):

Harald von Aschen	HvA	BfArM
Michael Horn	MH	BfArM

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[1] Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

[2] Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

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Deliverable abstract

Task 4.2 foresees the refactoring of the central German database for medicinal products (AMIS/AmAnDa) towards ISO IDMP and SPOR at the Federal Institute for Drugs and Medical Devices (BfArM).

The task includes work on the following topics:

- European-wide guidance how to standardise legacy data according towards IDMP and best-practices for other national competent authorities (NCAs) are drafted
- Essential tasks to provide ISO IDMP-compatible IT-systems are progressed based on national implementation plans
- Legacy data migration is progressed towards ISO IDMP based on national migration plans
- Essential tasks on data connectivity to EMA's SPOR services are progressed based on national implementation plans
- Increase knowledge and share best practices of how to implement ISO IDMP at NCA level

This report represents deliverable D4.4 and describes the status of the report period December 2019 to December 2020.

Keywords: BfArM, ISO IDMP, SPOR, REFACTORING

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List of abbreviations

Abbrevition	Complete form
AmAnDa	Arzneimittel- und Antrags-Datenbank
AMIS	Arzneimittelinformationssystem des Bundes
API	Application Programming Interface
BfArM	Federal Institute for Drugs and Medical Devices (German: Bundesinstitut für Arzneimittel und Medizinprodukte)
BMG	Federal Ministry of Health (German: Bundesministerium für Gesundheit))
BMEL	Federal Ministry for Food and Agriculture (German: Bundesministerium für Ernährung und Landwirtschaft)
BVL	Federal Office of Consumer Protection and Food Safety (German: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)
CTS	Communication and Tracking System
DCP	Decentralised Procedure
DIMDI	German Institute for Medical Information and Documentation (German: Deutsches Institut für Medizinische Dokumentation und Information
eAF	Electronic Application Form
EMA	European Medicines Agency
FHIR	Fast Healthcare Interoperability Resources
IDMP	Identification of Medicinal Products
IG	Implementation Guide
ISO	International Organization for Standardization
MAH	Marketing Authorisation Holder (German: Pharmazeutischer Unternehmer)
MP	Medicinal Product
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
OMS	Organisation Management Services
PEI	Paul-Ehrlich Institut – Federal Institute for Vaccines and Biomedicines (German: Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel)
PMS	Product Management Services
RDM	Relational Data Model designed by EMA for medicinal products (depreciated)

RMS	Referentials Management Services
SMS	Substance Management Services
SPOR	EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.
WP	Work package

Table 1. List of abbreviations

1 Executive summary

Task 4.4 foresees the refactoring of the core IT system for medicinal products (AMIS/AmAnDa) towards ISO IDMP and SPOR at the German Federal Institute for Drugs and Medical Devices (BfArM). This report represents deliverable D4.4 of the underlying Grand Agreement.

The BfArM is responsible for hosting the central German database for human and veterinary medicinal products on behalf of the three federal higher authorities BfArM, PEI (BMG) and the BVL (BMEL). Due to the age and the technical structure, there was an anticipated need for the development of a successor of this database, called AMIS. AMIS was a monolithic in-house development, and was finally decommissioned on 19 March 2020. The successor, AmAnDa, is a modular system using standard and in-house software, taking into account elements of ISO IDMP so far as this was known and possible during the development (e.g. substances, EU SPOR PMS IG v1, existing ISO IDMP data models). As usual for such complex replacement projects, there was a considerable delay in the development and roll-out, with a final and successful go life of AmAnDa on 23 March 2020.

In addition to this, there was in 2019 a political decision by the BMG to disband the DIMDI and to integrate its staff and task into the BfArM. The DIMDI was a federal higher authority, responsible for the development of software solutions and to provide essential databases for the public health care sector. This integration of the DIMDI (staff and IT structure/tasks) into the BfArM, resulting in a restructuring of the BfArM, was finalised on 10 July 2020.

Both events, together with the delay of the final adoption of the EU SPOR PMS IG v2 (anticipated February 2021) have resulted in the internal decision to slow down the speed on additional work to get the new database system AmAnDa further compliant with ISO IDMP. Planning and work has resumed with a higher speed in autumn 2020.

A detailed workplan with defined milestones for the project needs to be defined and is next on the agenda.

2 BfArM, Federal Institute for Drugs and Medical Devices

- BfArM is an independent federal higher authority, direct accountable to and supervised by the Federal Ministry of Health in Germany. The BfArM is responsible for
  - Authorisation and Post-marketing Activities (including Pharmacovigilance) for medicinal products for human use, Parallel Import of medicinal products, Complimentary and Traditional Medicinal Products and Standard Marketing Authorisations in Germany
  - Approval and supervision of clinical trials
  - The Federal Opium Agency and the Cannabis Agency
  - Innovation Office
  - Scientific research in the areas of Pharmacogenomics, Pharmacoepidemiology and Biostatistics
  - The Research Data Centre
  - Medical Devices – Pharmacovigilance and Databases
  - The DiGA(Digitale Gesundheitsanwendungen)-Fast-Track procedure ('Medical Apps')
  - The Centre of Semantics and Classification Systems (ICF, ICD, SnowMed CT, …)
  - Hosting the central database for human and veterinary medicinal products approved in Germany and the EU and provide information on this to the public and the health care sector
- Staff number: 1297 equivalent to 932 FTEs.

Key figures – Medicinal product Authorisations, Registrations, Parallel Traded

HUMAN		VETERINARY (for information and comparison purposes)	
Total:	72.070	Total:	2.550
MRP/DCP:	10.930	MRP/DCP:	890
National:	10.350	National:	1.430
Parallel import:	6.835	Parallel import:	20
Standard authorisation:	42.600	Standard authorisation:	90
Traditional MP:	285	Traditional MP:	5
Homeopathic:	1.070	Homeopathic:	115
Total:	**74.620**		

Table 2. Key figures by January 2021 – Medicinal product Authorisations, Registrations, Parallel Traded

Other key figures – Organisations and Substances

Complete Database	
Organisations total:	36.650
MAH:	16.100
Substances total:	45.800

Table 3. Key figures by January 2021

3 Task 4.3.: Progressing ISO IDMP implementation in AmAnDa

The new German database for human and veterinary medicinal products - called AmAnDa ("Arzneimittel- und Antrags-Datenbank") - has replaced the existing AMIS-system on 23 March 2020 after several years of planning and development.

As the AmAnDa-project has started well in advance of the UNICOM-project and is the key database, the first political priority was to finalise AmAnDa and to go live. This – together with the integration of the DIMDI – has blocked effectively a substantial amount of the available IT-Resources until March 2020 and some months afterwards.

AmAnDa was already designed in a modular approach based on principles of the ISO IDMP/SPOR and using the RDM. It consists of

- a substance database (S)
- a product database (P)
- a database on organisations called 'Partnerinformation' (O)
- a catalogue portal (R)

Taking into account the given constrains, the structured work on UNICOM WP4 and a further alignment of the data bases for products, organisations and referentials in AmAnDa has started with a significant delay.

3.1 Substances

As the need of a new architecture of the existing substance database materialised late in the AmAnDa development, there was the decision taken to use the ISO IDMP compatible and open source database G-SRS of the Ginas-project. This database in AmAnDa is called DE-SRS and has needed some adjustments to fit into the AmAnDa environment und to fulfil additional national necessary tasks. Experiences gained in the building of DE-SRS and tools created (loading tool of the existing substance data into DE-SRS, interaction with other elements of AmAnDa, …) are the fundamental basis for the building of EU-SRS (see UNICOM WP 2). Both projects have been and are running in close cooperation. DE-SRS is therefore the first ISO IDMP compatible database in real world daily use in the European Union.

There is already an internal decision to replace DE-SRS by EU-SRS if finalised and to be in line with any further software update and development of EU-SRS. No future national development of DE-SRS as substance database is anticipated. As result of this, amendments in DE-SRS based on national needs will be disintegrated, and established as independent software elements in AmAnDa.

3.2 Organisations and Referentials

A decision was taken in December 2020 to restart the mapping exercise between our

- database on organisations ("Partnerinformation") with EMA SPOR OMS and
- catalogue databases with EMA SPOR RMS

Taking into account the experiences of partners within WP 4 on available mapping tools, the decision was taken in December 2020 to license the tool 'Sporify'. This was followed by a preliminary decision in January 2021, to establish two new temporary BfArM-project positions for the mapping work (awaiting final agreement from the BfArM budget office).

3.3 Structure of AmAnDa

The practical construction and implementation of AmAnDa is based on a physical data model. A decision was taken in January 2021 to establish a logical data model for AmAnDa and to take this as the basis for further alignment with SPOR and especially with the SPOR PMS IG v2 expected to be published in February 2021.

3.4 Risks

#	Description of risk	Proposed risk-mitigation measures	Risk by Dec 2020 (L/M/H acc. GA)
1	Low availability of IDMP and NCA/EMA experts.	Intensive collaboration with consortium partners and, if needed, with external experts to clarify relevant topics.	H
2	Data migration towards IDMP delayed or scope must be reduced.	Adapt the scope of IDMP data migration to a minimum which is defined by the needs of the data consumers.	M
3	Due to national prioritisations and internal dependencies implementation of national tasks slows down or benefits from more financial resources.	Contribution monitoring of progress and consumption at NCA level. Possible reallocation of funding between tasks (NCA's) to mitigate risk and enhance progress where possible.	H
4	The high number of beneficiaries increases cross-WP communication efforts and alignment needs between the partners.	Shift resources from technical tasks to WP coordination. Optimise links and cross-fertilisation between WPs.	M
5	ISO IDMP identifiers needed for the univocal identification of medicinal products that depend on EMA publication and maintenance are not available.	Find replacement for these identifiers through direct collaboration with Drug NCAs of countries involved; substitute with MP data of repository piloted in WP9.	H
6	Different work packages are not aligned or progress at different paces thus affecting the outcome of WP4.	Increase alignment efforts between work packages. Regular - monthly - review meetings of timetable and progress.	M
7	Low availability of IT-Resources at NCA.	Acquire external resources, prioritize the project over other measures in the implementation period.	H
8	Low availability of subject matter experts at NCA due to the daily business.	Prioritization of tasks, broaden knowledge within the core team / key users	H
9	The complexity of the task was underestimated.	Apply agile approach to implementation, present interim results early and obtain feedback on an ongoing basis, willingness to reduce complexity through alternative solutions and/or appropriate prioritization in the backlog	M
10	Short-term changes in the scope of the project.	Trade off requirements, bring in additional resources	M
11	Important decisions are not made by the EU (SPOR API, EU IG v2...) or influence the project negatively.	Bringing this aspect to European working groups and boards.	H
12	Covid-19 measures, subject matter expert illness, lockdown.	Promote home office. Spread expertise, involve multiple developers	H

Table 4. Risks

3.5 Lessons learned

The implementation of ISO IDMP/SPOR turned out to be itself as a moving target and the investments are massive. Working together is essential and crucial, but even more important to learn from each other. The implementation of ISO IDMP/SPOR has to be based on more than one business case to be able to explore the full the full capacities of standards and even more important the power of harmonised high-quality data.