

## Short Public Report

1. Name and version of the IT-based service:

Mederi Network Intelligence Portal (MNIP), function as provided in March 2014

2. Vendor of the IT-based service:

Company Name:

Mederi AG - a Qforma company

Address:

Hanauer Landstr. 175-179

60314 Frankfurt am Main

Germany

Contact Person:

Nicole Morey

Executive Assistant & EU Office Lead

3. Time frame of evaluation:

From 7<sup>th</sup> October 2011 to 21<sup>st</sup> March 2014

4. EuroPriSe Experts who evaluated the IT-based service:

Name of the Legal Expert:

Dr. Hans Wolfram Kessler

Address of the Legal Expert:

kessler/stockhausen consulting limited

San Michel Building 2nd Floor, Suite 7

110, St. George's Rd.

St. Julian's

Malta

Name of the Technical Expert:

Dipl. Inform. Harald Löher

Address of the Technical Expert:

Bönnersdyk 12  
D-47803 Krefeld

5. Certification Body:

Name:

EuroPriSe Certification Authority

Address:

Joseph-Schumpeter-Allee 25  
53227 Bonn  
Germany

eMail:

contact@european-privacy-seal.eu

6. Specification of target of evaluation:

The Target of Evaluation covers:

- Mederi Network Intelligence Portal (MNIP)
- Kolibri web interface
- Mederi Analytics-Toolbox
- Deployment of hardware and software used to develop and run the Mederi service

The target of evaluation consists of all data processing regarding the service, starting from the

- collection of the data by freelancers and Mederi via the web-based service KOLIBRI, to
- the analysis of the collected data (Opinion Leader Mapping (OLM) and Market Access Intelligence (MAI) by Mederi and to the

- transfer of data to the customers via the web-based service Mederi Network Intelligence Portal (MNIP).

The target of evaluation also covers the legal aspects relating to the terms and conditions for customers and contracts with all third parties. It also includes the technical and administrative realization of the rights of affected data subjects as provided by Mederi.

Excluded from the target of evaluation are external, publicly available databases such as Pubmed: <http://www.ncbi.nlm.nih.gov/pubmed/> that are operated by third parties and queried by Mederi in order to gather information about so-called Key Opinion Leaders (KOL) and Market Access Stakeholders (MAS). Also excluded are the internal operations of data centres and any billing procedures as well as other services provided by Mederi, such as customer seminars and strategic counselling services.

## 7. General description of the IT-based service:

The target of evaluation is an IT-based service, the Mederi Network Intelligence Portal (MNIP), provided by Mederi AG, which delivers an Opinion Leader Mapping (OLM) and Market Access Intelligence (MAI) to Mederi customers. The service essentially aims at providing customers such as pharmaceuticals and other companies of the life-science-industry with information on key figures in the health market by analysing *and* structuring publicly available data on these persons. The analysis identifies two classes of data subjects: Key Opinion Leaders (KOL) and Market Access Stakeholders (MAS) by evaluating the interrelationships amongst the data subjects, their publications and other work related data. The analysis is then made available to Mederi customers via a web-based interface, the Mederi Network Intelligence Portal (MNIP).

The provision of service to customers involves the following four distinct data processing phases:

### Phase I: Identification of Key Opinion Leaders and / or Market Access Stakeholders

Based on the customer's needs and objectives (indication, geographical coverage, etc.), the field of interest is specified by the customer. Mederi's own Kolibri database (which contains only data on KOL / MAS that already have been collected from the public domain) then serves as a pool of potential Key Opinion Leaders (KOL) and Market Access Stakeholders (MAS). Further persons of interest to the customer are identified and Mederi then searches and analyses

the public domain for relevant data such as institutions specific to the field of interest, associations, workshops, congresses, scientific publications, clinical trials, medical guidelines, etc. to identify relevant stakeholders, augmenting the Kolibri database.

#### Phase II: Profiling of Key Opinion Leaders and / or Market Access Stakeholders

Profiling includes analysis of publications, trials, participation of events, memberships in disease-specific associations, such as professional societies and patient organizations. It must be emphasised that these memberships are only included with respect to the professional role of the relevant KOL/MAS and that social networks are not being searched. During this phase freelance workers are provided with names and positions of individual KOL or MAS in order to search the public domain for additional information on these data subjects. All relevant information is then fed into the Kolibri data base via the Kolibri web-interface with a secure connection via OPENSSSH.

#### Phase III: Network and Classification Analysis

Phase III consists of the actual processing of the data stored within the Kolibri data base (Phase II) by the Mederi analyst. On the basis of the field of interest specified by the customer a project specific subset from the Kolibri database is taken to populate a project specific, local database: the Analytics database. The Analytics Toolbox evaluates links between individuals based on their shared activities and aggregates multiple links between two individuals into one link with varying degrees of strength. Link strength may range from one, representing a weak connection, to four, representing a strong connection. This procedure is performed for each pair of individuals that have been identified as part of the OLU. According to the information stored on each data subject and on the calculated connections each individual is assigned a certain role.

The Analytics Toolbox also computes further information on OLs to classify them based on eight identified roles and the relevance of each individual in each role.

These roles include:

- Researcher
- Investigator
- Advisor

- Budget decider
- Approval decider
- Guideline maker
- Disease advocate

Results of the analysis process are then transferred to the MNIP database.

#### Phase IV: Visualisation of Network Intelligence

Phase IV comprises the delivery of the data and the analysis results to the customer. After completion of Phase III a project specific customer MNIP database can be accessed by the customer via the Mederi Network Intelligence Portal. Mederi's proprietary visualisation software enables clients to easily access Opinion Leader / Stakeholder profiles and networks. The Mederi Network Intelligence Portal (MNIP) is an easy-to-use tool which focuses on an intuitive search, visualization and analysis of networks, individuals' profiles, activities and classifications.

MNIP's key functions include

- Semantic search of
  - Opinion Leaders / Stakeholders
  - Institutions
  - Publications with abstracts and topic maps
  - Events, congresses, workshops and other activities
  - Scientific, patient and other associations
  - Local speeches and posters
  - Media activities
- Visualizations of
  - network graph – customized to display professional networks
  - map view – customized to display geographic networks
  - tabular view – customized to display structured information

8. Transnational issues:

MNIP is offered to customers worldwide on the basis of contracts which are concluded individually. Depending on the customer's place of location the use of MNIP may involve the transmission of personal data to a so-called "third country" that is neither member of the EU nor of the EEA. The individual contracts to be concluded between Mederi and the individual customer may have to be adapted accordingly.

9. Tools used by the provider of the IT-based service:

None

10. Edition of EuroPriSe Criteria used for the evaluation:

EuroPriSe Criteria Catalogue, Version November 2011

11. Evaluation results:

The evaluation showed that MNIP is in line with the high privacy standard set by the EuroPriSe Criteria Catalogue.

Fundamental issues (EuroPriSe Criteria Set 1):

MNIP encompasses a number of personal data processing operations. In a nutshell, Mederi processes data of key opinion leaders (KOL) and market access stake holders (MAS) in the medical and life-science-sector. Mederi AG acts as controller for each processing operation. The purpose of Mederi's data processing is, at the end, defined by Mederi's customers' needs. Transfer of data to customers only takes place on the basis of individual contracts concluded in view of the specific need of the individual customer. Mederi does not disclose the data to other so-called third parties. Mederi researches, collects and analyses only publicly available data and makes the results of the data gathering as well as the analytical process available to its customers as a service. Mederi's data processing operations do not take place outside the European Union and the European Economic Area. Making personal data available to its customers via the MNIP web-interface does, however, constitute a transmission of data under the EU Privacy Directive. As Mederi has customers worldwide, the relevant processing operations can, as the case may be, therefore constitute a transfer of data to third countries. This entails the need for specific safeguards which may

have to be on hand on a case-by-case basis, e.g. by EU standard contractual clauses. A resolution of Mederi's Management Board which provides guidelines on appropriate safeguards concerning transfers to third countries is in place.

Mederi's processing of data remains at all times strictly limited to the extent absolutely necessary in order to achieve the legitimate purpose of the relevant data processing operation. There is no other data processing operation which could equally achieve this purpose while at the same time being less intrusive on the data subjects' rights and interests. Being dedicated to data avoidance and data minimisation, Mederi does not search social media networks such as, for example, Facebook or XING. Sensitive data within the meaning of the EU Privacy Directive is not processed at all. In this respect, Mederi even excludes the processing of any Janus-faced personal data, i.e. data which relates to both the professional and private life of a data subject (only exceptions are first and last name as well as year of birth).

Inspections showed that the input forms used by Mederi and its reliance on published and publically available medical data bases remain restricted to data that is necessary for the Mederi MNIP service. No additional or unnecessary data is collected and processed. Mederi ensures transparency of its processing operations vis-à-vis data subjects in line with the EuroPriSe criteria. Data subjects concerned are informed about all relevant aspects in accordance with the EuroPriSe Criteria. A dedicated leaflet serves the purpose to make Mederi's customers aware of relevant data protection aspects.

#### Legitimacy of data processing (EuroPriSe Criteria Set 2):

Evaluation showed that all processing operations meet the conditions of article 7 of the EU Privacy Directive. In particular the core processing operations of MNIP are legitimate as they can be based on a balancing of interests-test. Thorough analysis of all processing operations within the target of evaluation proved that they are necessary for the purposes of the legitimate interests pursued by Mederi and they are not overridden by the interests of data subjects. Sensitive personal data within the meaning of article 8 of the EU Privacy Directive are not processed at all. The Directive's special requirements of data processing for certain purposes do not apply. The same holds true for the special restrictions on certain data processing operations under the EU's E-Privacy Directive.

MNIP also complies with the requirements for the various phases of data processing, especially data collection and data disclosure and ensures that data will be erased when no longer required. Data regarding key opinion leaders or market access stakeholders are collected from public sources only. As inspections showed, the sources are recorded along with each entry within the database. Internally, data are disclosed only to those who require access and only for the purpose for which the data were originally obtained. Data are only passed on to the specific customer and to no other third party. Mederi takes all necessary steps in order to ensure that all data is up to date. Within the framework of the EuroPriSe certification process, Mederi has, in addition, implemented a new correction and erasure routine.

MNIP complies with all general data protection principles and –duties. Data are collected for specified, explicit and legitimate purposes only. The purpose of any transmission of data to a customer by way of disclosure via the MNIP web-interface is laid down in the respective individual contract. EuroPriSe's high standards regarding proportionality and quality of data are met.

In respect of special types of processing operations (i.e. the processing of data by a processor, any transfer of data to third countries and automated individual decisions), evaluation showed that all applicable requirements are met.

All legal formalities regarding data processing have been complied with.

Technical-organisational measures – accompanying measures for protection of the data subject (EuroPriSe Criteria Set 3):

The evaluation assessed in detail the following technical aspects of the target of evaluation:

- physical access control;
- access to media and mobile devices;
- access to data, programs and devices;
- identification and authentication;
- use of passwords;
- organisation and documentation of access control;
- logging and logging mechanisms;



- network and transport security;
- back-up- and recovery mechanisms;
- data protection and security management (including requirements concerning the client's security policy and risk assessment);
- documentation and inventories;
- media management;
- the appointment and duties of a security officer;
- instruction of personnel, and the imposition of a formal duty of confidentiality on them;
- the carrying out of a data protection and security audit;
- incident management;
- test and release;
- disposal and erasure of data; and
- temporary files.

Measures and safeguards for preventing unauthorised access to data, premises and devices are in place and have been found to be adequate. Roles have been defined to separate responsibilities and permissions and to match these to tasks.

Logging and logging mechanisms have been found to be adequate but as a result of the evaluation retention periods for log data have been defined in the *Richtlinien für das Kolibri-Logging, Stand: Dezember 2011*.

Network and Transport Security have been found to be excellent as remote access to Mederi internal systems and access to service providers systems for Mederi staff is only possible via an encrypted VPN channel employing digital certificates and web-access for researchers and customers is via HTTPS.

Mechanisms and safeguards to prevent accidental loss of data, back-up mechanisms and recovery have been found to be adequate.

Data protection and security management have been found to be mostly adequate. Security policies are in place, enacted and supported by the Mederi CEO and documented in binding guidelines:

- IT-Sicherheitsrichtlinie der Mederi AG

- Sicherheitsrichtlinie zur Nutzung von Notebooks
- Sicherheitsrichtlinie zur Internet-Nutzung
- Sicherheitsrichtlinie zur IT-Nutzung

Due to the character of the primary data processed (publicly available data) a written risk analysis is considered not mandatory.

Inspection by the technical expert showed that obligations and duties are documented and assigned to an individual. As a result of the audit findings Mederi has agreed to document the execution of performed backups and who is responsible for it.

Mederi keeps an up-to-date inventory of servers, laptops and software and guidelines for the management of media which was found to be adequate.

An independent data protection officer is appointed in conformance with national legislation. Instruction / Training for new employees is obligatory and formalised and data protection and data security matters are investigated only if suspicion has been raised. This has been found to be adequate regarding the nature of the data processed.

Test and release procedures follow a defined release process and have been found to be adequate.

Business sensitive data including personal data is encrypted but the disposal of data carriers and erasure of data is performed following a secure deletion routine and temporary files are deleted automatically, which has been found to be adequate.

For customers the service is documented in a manual, for researchers a Research-Wiki exists, both found to be adequate.

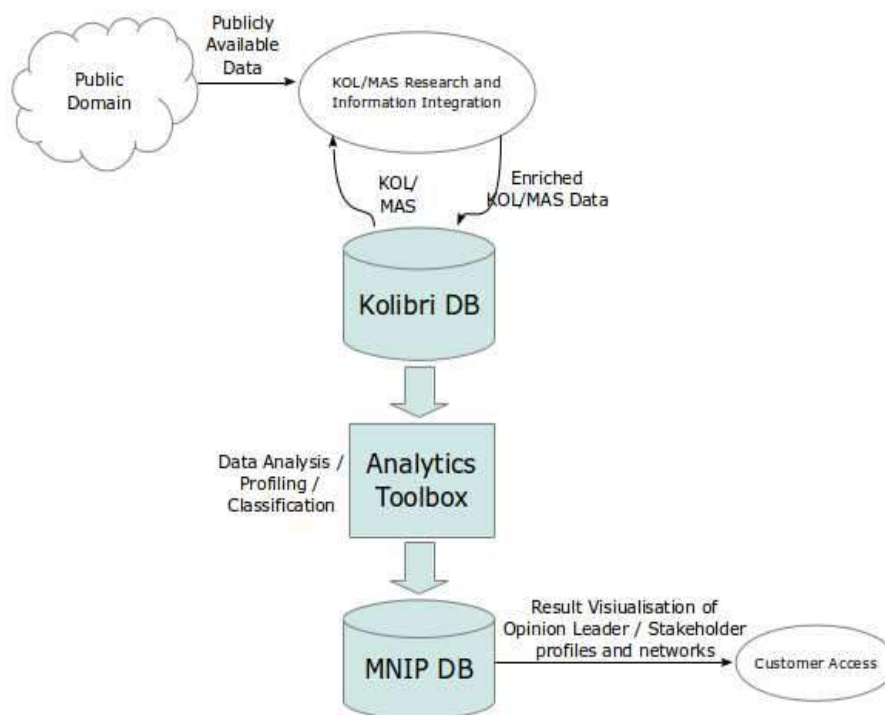
As the purpose of the service is to collect and analyse personal data it is adequate that data are neither anonymised nor pseudonymised.

#### Data subjects' rights (EuroPriSe Criteria Set 4):

Mederi has implemented efficient technical-organisational measures in order to ensure the fulfilment of data subjects' rights under the EU Privacy Directive. Mederi informs data subjects whose data are collected in accordance with the strict EuroPriSe criteria. Prompted by the EuroPriSe certification process, Mederi has also implemented a new organisational framework for the swift and

competent handling of any requests by data subjects to be provided with access to or to correct or erase their personal data. In the same vein, Mederi has enhanced its own data erasure routines. Data of data subjects which has not been updated for four years will be deleted automatically. Furthermore, customer projects in the MNIP database will, at the latest, be deleted at the latest three years after the contract with the respective customer has finished.

12. Data flow:



13. Privacy-enhancing functionalities:

The main privacy enhancing feature of the service is that only publicly available data are collected, processed and made available to customers and that these data concern professional facts about the data subjects only. Mederi internally ensures that personal data concerning the private life of data subjects are not stored. Facts or hints indicating that these safeguards are not efficient have not been found.

Another important privacy enhancing feature is the complete separation of data collection and update in the Kolibri database from the data retrieval by customers via a dedicated database (MNIP).

14. Issues demanding special user attention:

There are no issues to which users of the service should pay special attention.

15. Compensation of weaknesses:

The evaluation identified the absence of a written risk analysis as (the only) potential weakness. But it is evident that an implicit risk analysis has been performed given the fact that only publicly available data is being processed and made available to Mederi customers, that design decisions have been made and sufficient safeguards have been implemented to achieve adequate provision of data protection issues. This is found to compensate for the non-existing written risk analysis.

All interviewed Mederi employees are aware of the importance of data protection principles and, as far as observed, obey them. This obviously has led to a design of service and infrastructure with complete separation of data input- and update-operations via the Kolibri interface on the Kolibri database and the data retrieval by customers via the MNIP interface on the MNIP database.

16. Decision table on relevant requirements:

<b><i>EuroPriSe Requirement</i></b>	<b><i>Decision</i></b>	<b><i>Remarks</i></b>
Data Avoidance and Minimisation	adequate	processing of publically available data from a mere professional context only  business interests do not contravene, but reinforce proportionality of data processing  no processing of data published in social media networks
Transparency	adequate / excellent	information of data subjects improved within the framework of the EuroPriSe certification process
Technical-Organisational Measures	adequate	benefitting from the nature of the data processed
Data Subjects' Rights	excellent	organisational framework for the handling of data subjects' rights improved during the EuroPriSe certification process

## Experts' Statement

We affirm that the above-named IT product / IT-based service has been evaluated according to the EuroPriSe Criteria, Rules and Principles and that the findings as described above are the result of this evaluation.

St. Julian's, 25/03/2014    Dr. Hans Wolfram Kessler

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Place, Date	Name of Legal Expert	Signature of Legal Expert
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Krefeld, 25/03/2014    Harald Löher

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Place, Date	Name of Technical Expert	Signature of Technical Expert
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## Certification Result

The above-named IT product / IT-based service passed the EuroPriSe evaluation.

It is certified that the above-named IT product / IT-based service facilitates the use of that product or service in a way compliant with European regulations on privacy and data protection.

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Place, Date	Name of Certification Authority	Signature
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