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# Document History

Version	Date	Status	Change
1.0	19-Nov-2019	Released to customer	Initial release
1.1	15-May-2020	Final	Updates: <ul style="list-style-type: none"><li>• MDLP integrated Scenario</li></ul>

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## Legal Disclaimer

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# 1 About this Document

## 1.1 Purpose and Scope

This document describes the Service for the Russian Drug Circulation Monitoring System (MDLP) used by manufacturers interacting on the SAP Information Collaboration Hub for Life Sciences in Russia.

This document describes current MDLP processes supported by SAP.

## 1.2 Assumptions

A Prerequisite is knowledge of the MDLP in the Russian market.

## 1.3 Target Audience

This document is for customers and partners of the SAP Information Collaboration Hub for Life Sciences who use the Russian Regulatory Reporting service, including:

- Integration experts
- Implementation teams
- SAP ATTP Configuration experts and administrators

## Related Information

- SAP InfoHub Russian MDLP ATTP Configuration Guide on the [Regulatory Reporting Help page](#)
- [SAP Information Collaboration Hub for Life Sciences Help Portal](#)
- [SAP Information Collaboration Hub for Life Sciences Onboarding Wiki](#)
- [SAP Advanced Track and Trace for Pharmaceuticals Help Page](#)
- [CRPT Landing Page on Track & Trace](#)

## 1.4 Glossary

Abbreviation	Definition
3PL	Third Party Logistics service provider
ATTP	SAP Advanced Track and Trace for Pharmaceuticals
CMO	Contract Manufacturing Organization
CRPT	Company that runs MDLP service
EPC	Electronic Product Code, often used to summarize different formats of unique identifiers
EPCIS	Electronic Product Code Information Services - GS1 Standard, refer to <a href="http://www.gs1.org/epcis/epcis/1-1">http://www.gs1.org/epcis/epcis/1-1</a> . This specification is based on EPCIS 1.1
GCP	Global Company Prefix (GS1 Standard)
GLN	Global Location Number (GS1 Standard)
GS1	<a href="#">Global Standardization Body</a>
GTIN	Global Trade Identification Number (GS1 Standard)
ICH	SAP Information Collaboration Hub for Life Sciences
LIS	Russian state information system created for the purpose of information support of CIM labeling of products
MAH	Marketing Authorization Holder
MDLP	Supply Chain Reporting System in Russia for Pharmaceutical Industry
SGTIN	Serialized GTIN, special case of EPC
SSCC	Serial Shipping Container Code
OMS	Order Management Station

## 1.5 Typographic Conventions

Type Style	Description
	This icon indicates that there is information in an MAH specific document. Certain processes or options vary and depend on the preference of the MAH.
<i>Example</i>	Words or characters quoted from the screen. These include field names, screen titles, pushbuttons labels, menu names, menu paths, and menu options. Textual cross-references to other documents.

Type Style	Description
<b>Example</b>	Emphasized words or expressions.
EXAMPLE	Technical names of system objects. These include report names, program names, transaction codes, table names, and key concepts of a programming language when they are surrounded by body text, for example, SELECT and INCLUDE.
Example	Output on the screen. This includes file and directory names and their paths, messages, names of variables and parameters, source text, and names of installation, upgrade and database tools.
<b>Example</b>	Exact user entry. These are words or characters that you enter in the system exactly as they appear in the documentation.
<Example>	Variable user entry. Angle brackets indicate that you replace these words and characters with appropriate entries to make entries in the system.
EXAMPLE	Keys on the keyboard, for example, <b>F2</b> or <b>ENTER</b> .

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## 2 Introduction

Early 2017, the Chairman of the Government of the Russian Federation signed a decree on conducting an experiment on marking drugs with control (identification) signs, and monitoring the turnover of certain types of medicinal products for medical use. As a result of the experiment, a system called “MDLP” for monitoring the movement of medicinal drugs use has been developed. Reporting to this system became mandatory in 2018 for certain products, and starting January 1<sup>st</sup>, 2020, will cover all drugs in the Russian market.

SAP Advanced Track and Trace for Pharmaceuticals (ATTP) focuses on message content, SAP Information Collaboration Hub for Life Sciences provides connectivity to MDLP.

SAP Information Collaboration Hub for Life Sciences is an innovative on-demand solution that connects pharmaceutical organizations and their supply chain partners on a secure network that is owned and managed by SAP, and supports the transfer and transformation of serialization messages between members of the pharmaceutical supply chain. SAP Information Collaboration Hub for Life Sciences also supports the transfer of formatted messages to government or institutional databases and systems such as MDLP.

### 2.1 Business Scenarios

The SAP Information Collaboration Hub for Life Sciences allows communication to MDLP. The service supports the following business scenarios with HTTP *POST* operations:

- Submit Foreign Messages:
  - 312 - Register\_control\_samples
  - 331 – Foreign Shipment
  - 333 – Foreign Import by Owner
  - 351 – Change of Ownership
  - 701 – Acceptance
  - 911 – Unit Pack
  - 912 – Unit Unpack
  - 913 – Unit Extract
  - 914 – Unit Append
  - 915 – Multipack
- Submit Domestic Messages:
  - All relevant message types are supported. For more information, see [SAP Advanced Track and Trace for Pharmaceuticals Release 2.0, Feature Package 5: Messages and Changes for MDLP Reporting](#)

### 2.2 Supported Industries

The following industries are supported for connection and data exchange with MDLP:

- Pharmaceutical Industry

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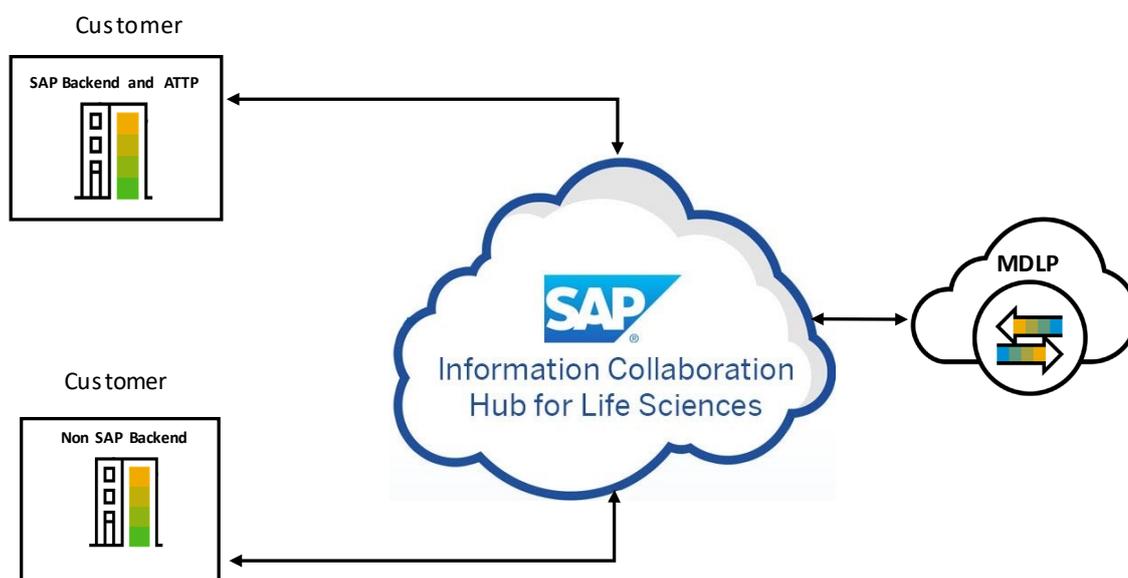
For other industries, there are different marking systems.

### 3 Service Overview

The MDLP Regulatory Reporting service of the SAP Information Collaboration Hub for Life Sciences is available to customers who wish to connect:

- An SAP backend system such as SAP Advanced Track and Trace for Pharmaceuticals
- A non-SAP backend system

The following figure summarizes connection possibilities:



The SAP Information Collaboration Hub for Life Sciences routes reporting messages to MDLP including the following features:

- Connection to secure HTTPS endpoints for production and test environments
- Connection to non-secure HTTP endpoints if provided, only in sandbox environments
- Error handling and monitoring on technical message level

#### Requirement

You must send messages that comply with the MDLP message format.

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## 3.1 Key Benefits

The key benefits are as follows:

1. **Onboarding to Regulatory Services:**
  - a. Fast onboarding to MDLP based on SAP ATTP RU-core capabilities
  - b. Reduced testing effort based on qualified gateway functionality
  - c. Service managed by SAP
2. **Simplified Connectivity** to MDLP Systems:
  - a. Communication to MDLP in secure and non-secure mode
  - b. Automatic token administration upon request
3. **CRPT Certified Solution** with hosted MDLP Marking system
4. **Integration with SAP ATTP** out-of-the-box

## 3.2 Service Versions

There are two versions of the SAP Regulatory Reporting Service for MDLP:

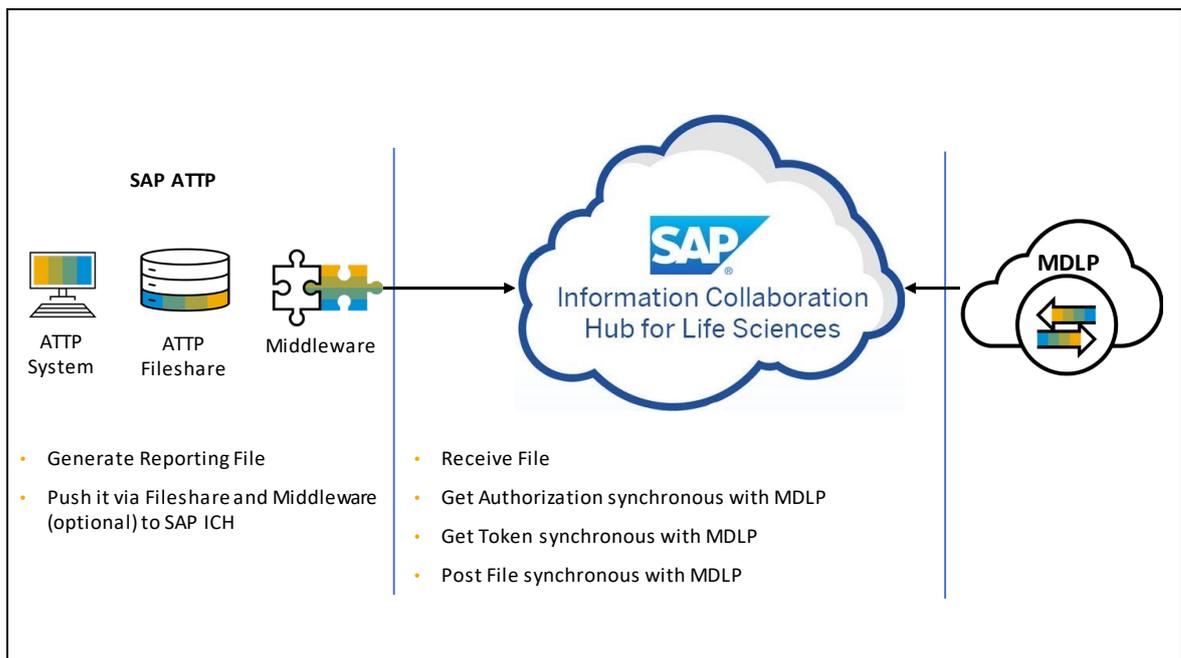
- Version 1 Supports file-based messaging, which is the only option for customers on SAP ATTP 2.0, FP4.
- Version 2 Supports automatic Webservice-based connection, available for customers with ATTP 2.0 FP5 or higher

### 3.2.1 Version 1 FP5 or Lower

Version 1 is recommended for customers that run SAP ATTP in a version lower than ATTP 2.0 FP5.

In ATTP FP04, ATTP generates Reporting Files for MDLP. The files are then stored on a Fileshare and pushed via an optional Middleware to SAP ICH where the files are received, and communication to the MDLP Server is synchronous.

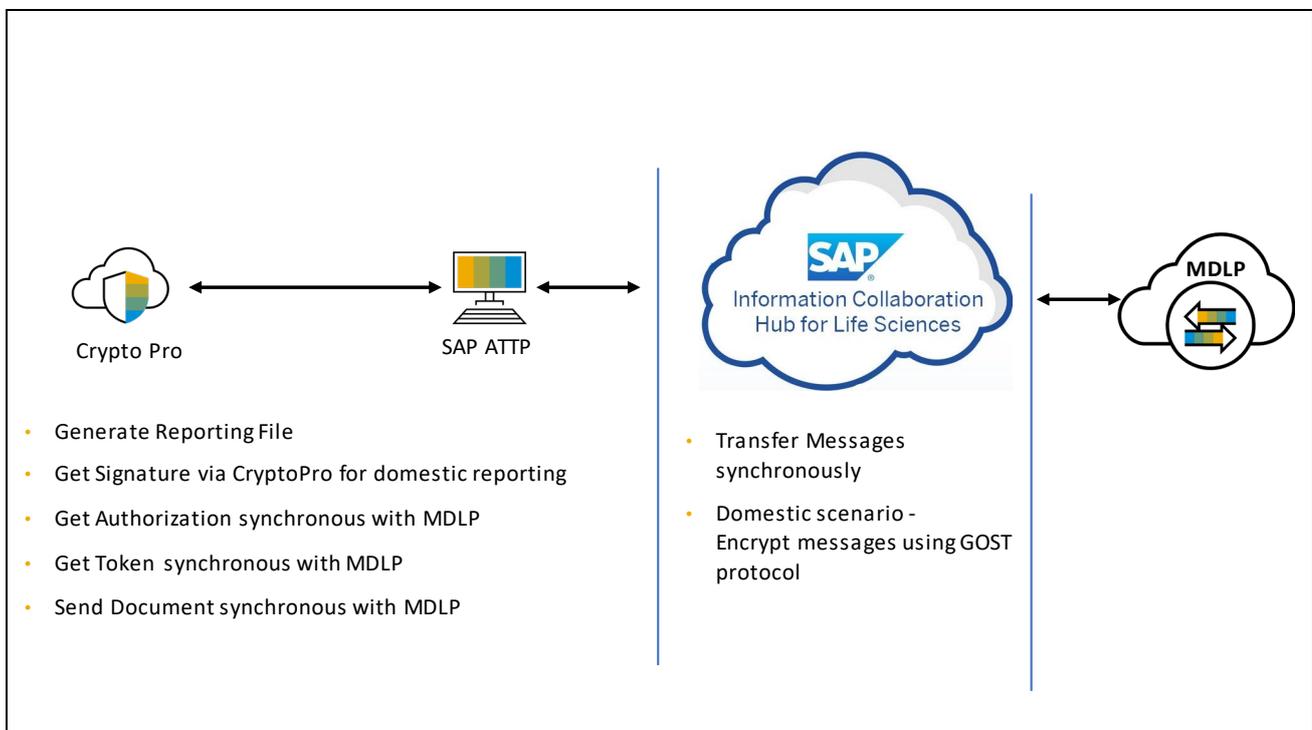
The following graphic shows Version 1, FP05 or lower.



## 3.2.2 Version 2 FP5 or Higher

Version 2, ATTP 2.0 FP5 or higher, supports automatic Webservice-based connection.

Release ATTP 2.0, Feature Pack 05 includes the option to submit Domestic Reporting Messages. This option came with a change in the whole scenario. Instead of only generating the reporting file, the communication with MDLP is now managed in the ATTP system as opposed to the purely file-based handling in FP4. For reporting a file of type Domestic, the message must be signed, for example via CryptoPro, to fulfill the requirements for submission to MDLP. With SAP ATTP 2.0 FP5, there is the possibility to distinguish foreign and domestic reporting messages for Russia Reporting by introducing new System Types. The Service for Regulatory Reporting then submits the file to MDLP and performs the GOST-based encryption for domestic Reporting messages. The following graphic illustrates the process.

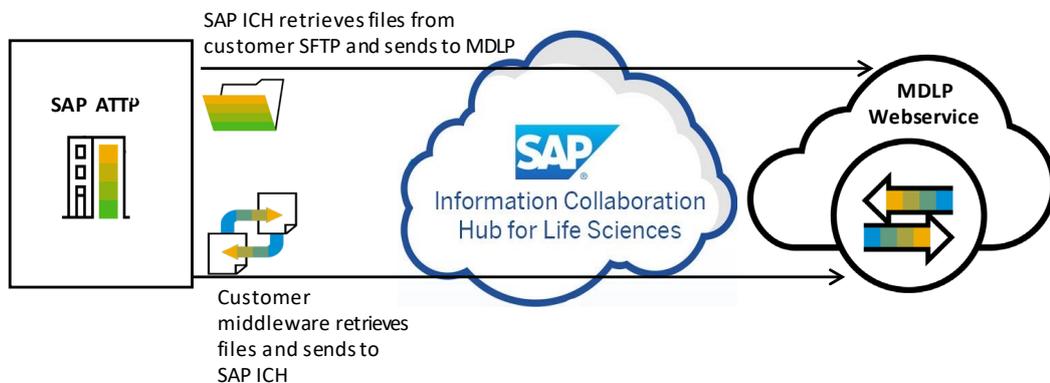


## 3.3 SAP Message Orchestration

### 3.3.1 Version 1: Foreign Reporting via Fileshare (FP04)

The SAP Information Collaboration Hub for Life Sciences (ICH) handles messages that are sent synchronously to the MDLP System. The file export option in SAP ATTP FP4 is used to generate the message files. SAP provides the following options to send message files to the SAP Information Collaboration Hub for Life Sciences:

- Set up SFTP folder from which SAP ICH retrieves files and distributes the files to MDLP
- Set up a middleware channel, take the files and forward them to SAP HTTP interface



### 3.3.2 Version 2: Foreign and Domestic Reporting Integrated Scenario (FP05)

A new communication scenario from ATTP to MDLP through the SAP Information Collaboration Hub for Life Sciences was introduced with ATTP FP05:

Instead of an SFTP folder and SOAP Network Protocol, the reporting files are directly transmitted to MDLP through SAP ICH via a REST-based Webservice.

A Fileshare or Middleware is not required. Due to the complexity of the scenario and the different authorization-related headers needed to authenticate at SAP ICH as well as the MDLP System, SAP recommends a direct connection between SAP ATTP and SAP ICH. SAP does **not** support issues related to Middleware in this scenario.



For Domestic messages sent to MDLP via SAP ICH, the reporting notifications must be signed in SAP ATP, and are encrypted in SAP ICH using GOST on SAP Private Cloud Infrastructure in Russia which is mandatory for domestic message exchange.

GOST, defined in the standard GOST 28147-89 (RFC 5830), is a Russian government standard symmetric key block cipher with a block size of 64 bits.

## 4 Applicable GxP Requirements

The SAP Information Collaboration Hub for Life Sciences is not a system of record, and therefore, can be regarded as a system with low risk with regards to GxP. Nevertheless, data transmitted may be GxP relevant so basic GxP principles for developing and operating the system are applied.

GxP Factor	Status
Audit trail	n/a, data is not changed, logging is available for 30 days
Electronic Signatures	n/a
Security Requirements	For Routing: certificates expiring For Reporting App: - Password change required, length - User authentication - Logging and locking
Development	SAP Quality Management System applies
Operations	SAP Cloud Platform is SOC1, SOC2 and ISO 27001 certified.

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# 5 Main Functions

This section describes the main functions for Version 1 and Version 2.

## 5.1 Version 1: Foreign Reporting via Fileshare (FP04)

### 5.1.1 Connection Credentials

For Service Version 1, to establish a successful connection to the MDLP system the following parameters are mandatory for the service managed connection on SAP ICH:

- Subject ID (Member registration number)
- Client ID
- Client Secret
- User ID (mail address)
- User Password

#### Subject ID:

The subject id can be retrieved from MDLP account in section *PROFILE* and is described by the *MEMBER REGISTRATION NUMBER*.

#### Client:

To create a new client and client secret follow the steps:

1. Go to Administration in MDLP
2. In Tab "Accounting systems" create a system
3. To get client secret, click on the \*\*\*\*\* in related field

#### User:

How to create a new user ID:

1. Go to Administration in MDLP
2. In Tab "Users" create a new user

### 5.1.2 Service Definitions

The SAP Information Collaboration Hub for Life Sciences allows communication to MDLP. The service supports the following business scenarios with HTTP *POST* operations:

- 
- Submit Foreign Messages:
    - 312 - Register\_control\_samples
    - 331 – Foreign Shipment
    - 333 – Foreign Import by Owner
    - 351 – Change of Ownership
    - 701 – Acceptance
    - 911 – Unit Pack
    - 912 – Unit Unpack
    - 913 – Unit Extract
    - 914 – Unit Append
    - 915 – Multipack

## **5.1.3 Technical Framework**

### **5.1.3.1 Communication Patterns**

The service communicates with the MDLP synchronously. Connection to SAP Information Collaboration Hub for Life Sciences must can be synchronous or asynchronous for the decoupled set up based on file export functionality in SAP ATTP. Message distribution is planned for future synchronous only.

### **5.1.3.2 Access Management**

The service connection is based on trusted certificates as authorization method.

### **5.1.3.3 Message Routing**

The service supports routing of MDLP related HTTP Post requests to the correct service endpoint of the MDLP with the necessary credentials.

### **5.1.3.4 Message Validation**

The service accepts messages that are generated in the correct format, specified by CRPT. There is no message validation on the content. All checks required are in place in SAP ATTP and in MDLP.

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## **5.1.3.5 Performance Requirements**

The service processes files according to MDLP specification requirements.

## **5.1.3.6 App Access**

The current version of the SAP MDLP service contains no applications.

## **5.1.3.7 Single Sign On**

This is not applicable for this version of the SAP MDLP service.

## **5.1.3.8 Alarms and Alarm Notifications**

### **5.1.3.8.1 Exception Alarms**

The service raises alarms in case of failed events. Technical errors are investigated by the SAP Support team. Functional errors are investigated solely by customers.

### **5.1.3.8.2 Alarm Notifications**

The SAP Support team receives notifications in the event of technical exception events.

## **5.1.3.9 Technical Communication**

### **5.1.3.9.1 AS2**

AS2 communication is not supported.

## 5.1.3.9.2 HTTP

The service can communicate using HTTP calls.

## 5.2 Version 2: Foreign and Domestic Reporting integrated Scenario (FP05)

As described in previous sections, a new integrated MDLP Reporting scenario was introduced with SAP ATTP FP05. The main functions of this new scenario are:

- Support of Domestic Messages via Signature Process with CryptoPro
  - Distinction between Foreign and Domestic in ATTP using new system types:
    - D – Domestic Reporting System
    - F – Foreign Reporting System

System Description	Status	System Type	System Grp L
Russia MDLP Domestic Syste...	1 - Active	D - Domestic Reporting System	SAP_RU_PH
Russia Foreign MDLP System...	1 - Active	F - Foreign Reporting System	SAP_RU_PH

- Encryption of Reporting Messages using GOST protocol
- Integrated Communication between ATTP and MDLP through SAP ICH via REST-based Webservices and direct connection. SAP recommends no middleware.

### 5.2.1 Connection Credentials

For Service Version 2, MDLP credentials do not need to be communicated to the SAP Onboarding Team, because credentials are part of the standard SAP ATTP 2.0 FP5 setup.

### 5.2.2 Messages Supported

For foreign and domestic reporting notifications, all messages that are supported by the latest version of SAP ATTP can be exchanged via SAP ICH. See the relevant section of the [SAP ATTP Configuration Guide for Russia Reporting](#).

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## 5.2.3 Technical Framework

### 5.2.3.1 Communication Patterns

The service communicates with the MDLP synchronously. Connection to SAP Information Collaboration Hub for Life Sciences must also be synchronous.

### 5.2.3.2 Access Management

The service can be used by S or P users that a customer provides. These users can send MDLP related REST calls to the SAP endpoint provided. These users have no other authorizations

### 5.2.3.3 Message Routing

The service supports routing of MDLP related HTTP Post requests to the correct service endpoint of the MDLP with the necessary credentials.

### 5.2.3.4 Message Validation

The service accepts messages that are generated in the correct format, specified by CRPT. There is no message validation on the content. All checks required are in place in SAP ATTP and in MDLP.

### 5.2.3.5 Performance Requirements

The service processes files according to MDLP specification requirements.

### 5.2.3.6 App Access

The current version of the SAP MDLP service contains no applications.

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## 5.2.3.7 Single Sign On

This is not applicable for this version of the SAP MDLP service.

## 5.2.3.8 Alarms and Alarm Notifications

Monitoring capabilities are provided within SAP ATTP. As the connection to MDLP is fully synchronous, error messages will be visible within the Application Interface Framework. As part of the standard functionality, customers can configure alerting based on customer-specific criteria.

### 5.2.3.8.1 Exception Alarms

The service raises alarms in case of failed events. Technical errors are investigated by the SAP Support team. Functional errors are investigated solely by customers.

### 5.2.3.8.2 Alarm Notifications

The SAP Support team receives notifications in the event of technical exception events.

## 5.2.3.9 Technical Communication

### 5.2.3.9.1 AS2

AS2 communication is not supported.

### 5.2.3.9.2 HTTP

The service can communicate using HTTP calls.

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## 6 Important Disclaimers and Legal Information

### 6.1 Coding Samples

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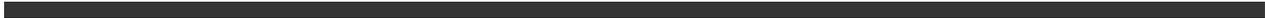
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