



# UDI Platform

Managed Service on SAP Cloud Platform

# About Unique Device Identification (UDI)

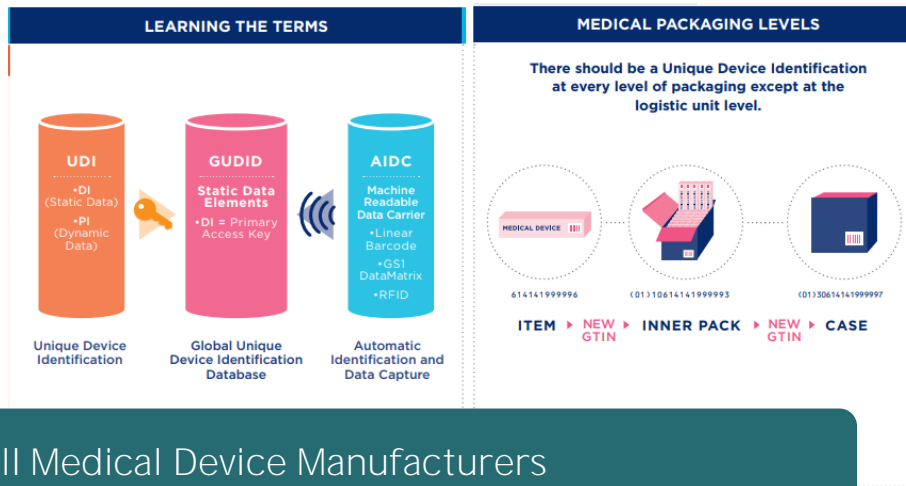
UDI is already mandatory in USA and is part of EU Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR)

- UDI helps identifying products (via Label) and publishing product master-data in public databases

## Goals

- Improve patient safety
- Improve recall processes
- Improve Market surveillance

FDA example



Mandatory for all Medical Device Manufacturers

# The global UDI Challenge



5

## Few Years

Many more UDI Regulations are in works



## A Puzzle

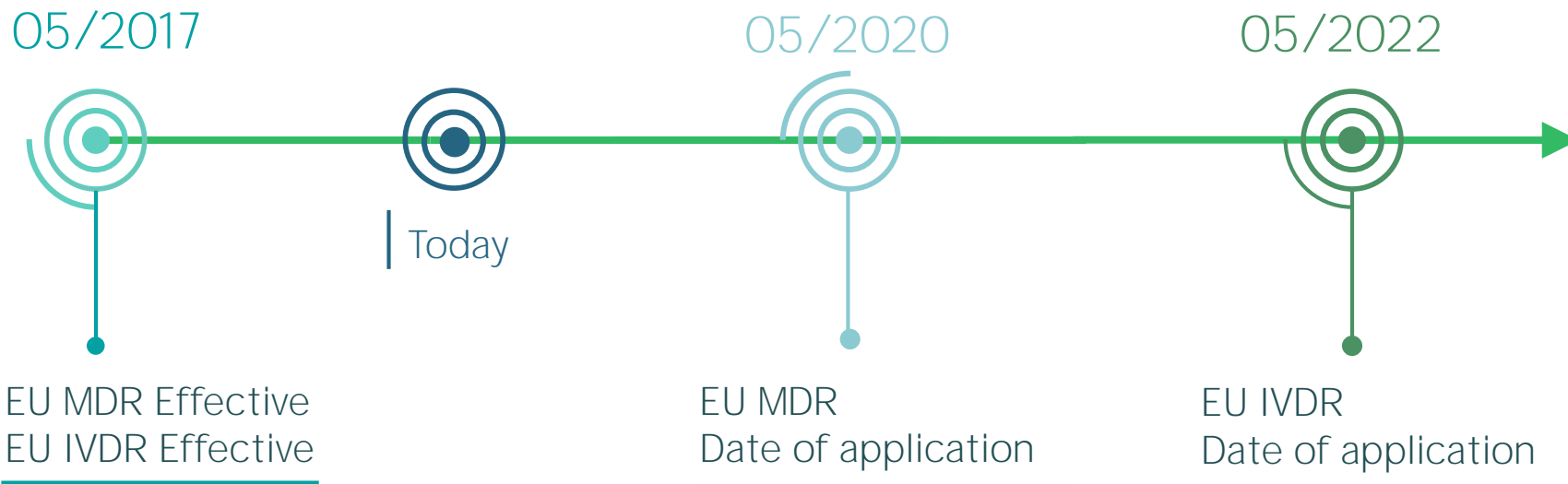
Which Authority demands what and when?



## Different...

Different Data Models, different UDI Databases

# EU MDR / IVDR Transition Periods



# What does that mean for you?

## Market Monitoring

Always stay tuned to not miss any information / requirements



## New Requirements

New authorities have different requirements – capture them and plan the implementation



## Unclear Timelines

When will new implementation guides be published?



## Close Deadlines

Stay compliant and keep the deadlines of all authorities



## More Development

Have enough developers ready for the upcoming implementations



## New Interfaces

Supply all authorities in different ways



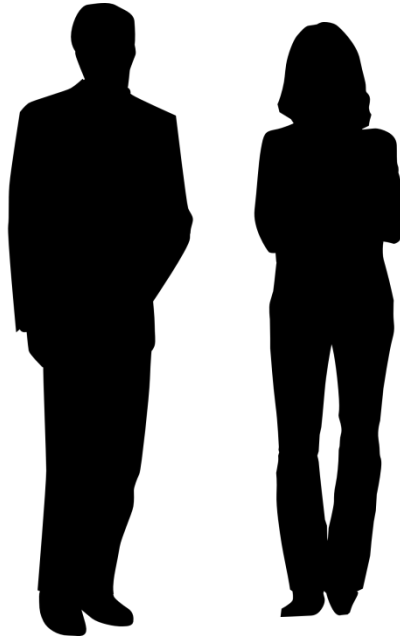
## More Updates

Ensure that pending changes are implemented during operation



## More Support

Be aware that the support effort will increase with each additional authority



# 6 reasons for a managed UDI Cloud Solution

1

Concentrate on your Core Business

The requirements affecting your UDI Processes are driven by external Authorities. A managed Cloud Solution is close to the market and implements all requirements timely.

2

Less Support effort

An externally managed Cloud solution includes Support and relieves the burden on your Support Organization.

3

Simplified Ressource Planning

A managed Cloud Solution scales for you with every regulatory Authority. You neither need new hardware nor Software Development Ressources.

## 6 reasons for a managed UDI Cloud Solution

4

### Calculable Costs

A Cloud Provider offers transparent licensing metrics for the Service Subscription. You achieve Planning security on your whole UDI Lifecycle.

5

### Clear Test and Change Management

A managed Solution ensures the majority of tests during Changes of the UDI Process. A clear Change Request Handling and traceability ease to estimate the Regression Test efforts for you.

6

### Compliance

A managed Solution covers all requirements on the submission handling to UDI Databases worldwide – you can concentrate on the data preparation.

# One UDI Platform for all Regulatory Authorities



**New Regulatory Authorities**  
The specific requirements of the different authorities will always be timely implemented



**Changes**  
Forced changes by the authorities will be covered and you will be informed proactively



**New Interfaces to Authorities**  
Will be implemented without affecting your interface to the service



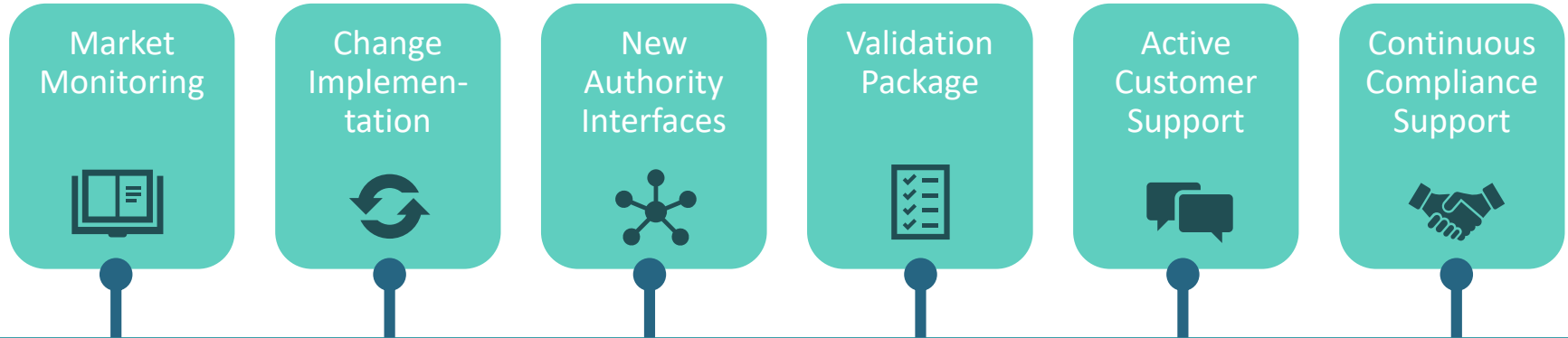
**Your Data**  
Your data will stay your data. You will be supported in transforming the data into the authorities' data models



**Your Processes**  
Link your existing master-data processes to the Cloud-Service



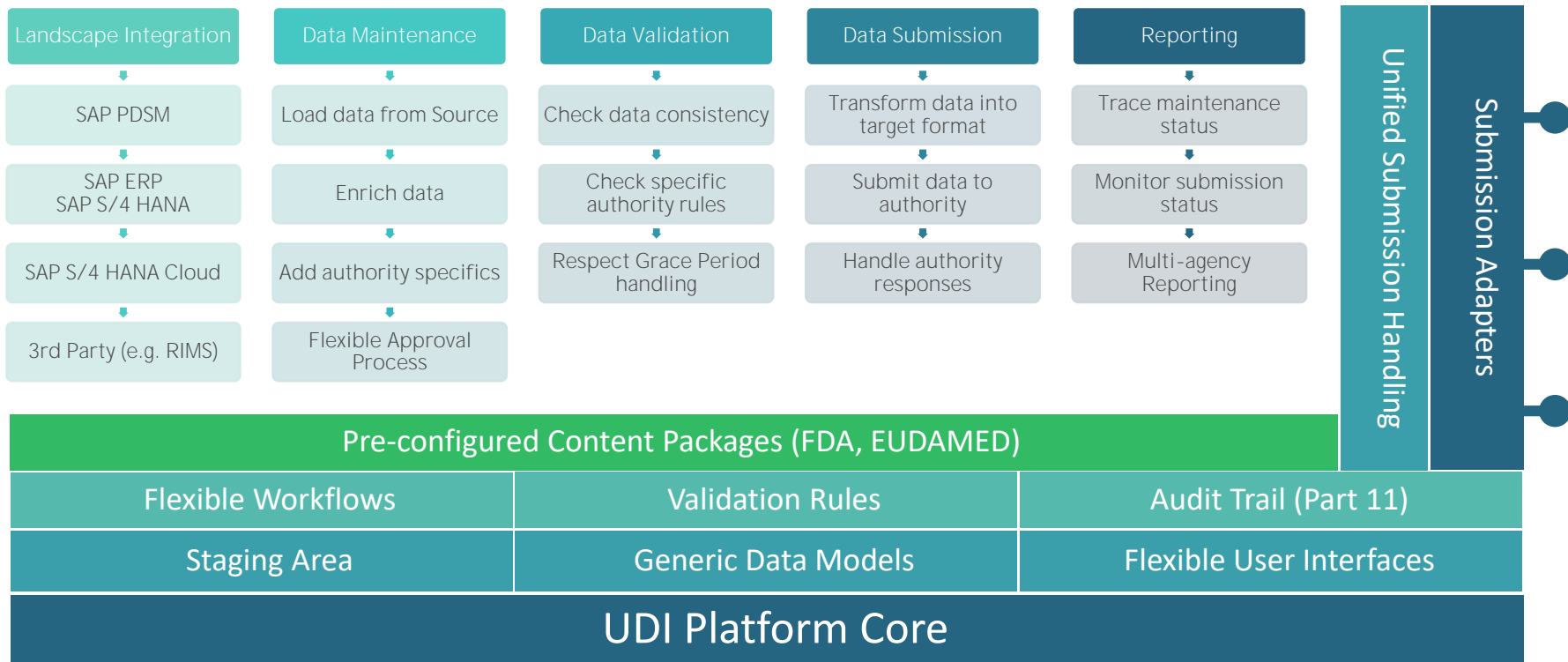
# We care - our Managed Service approach



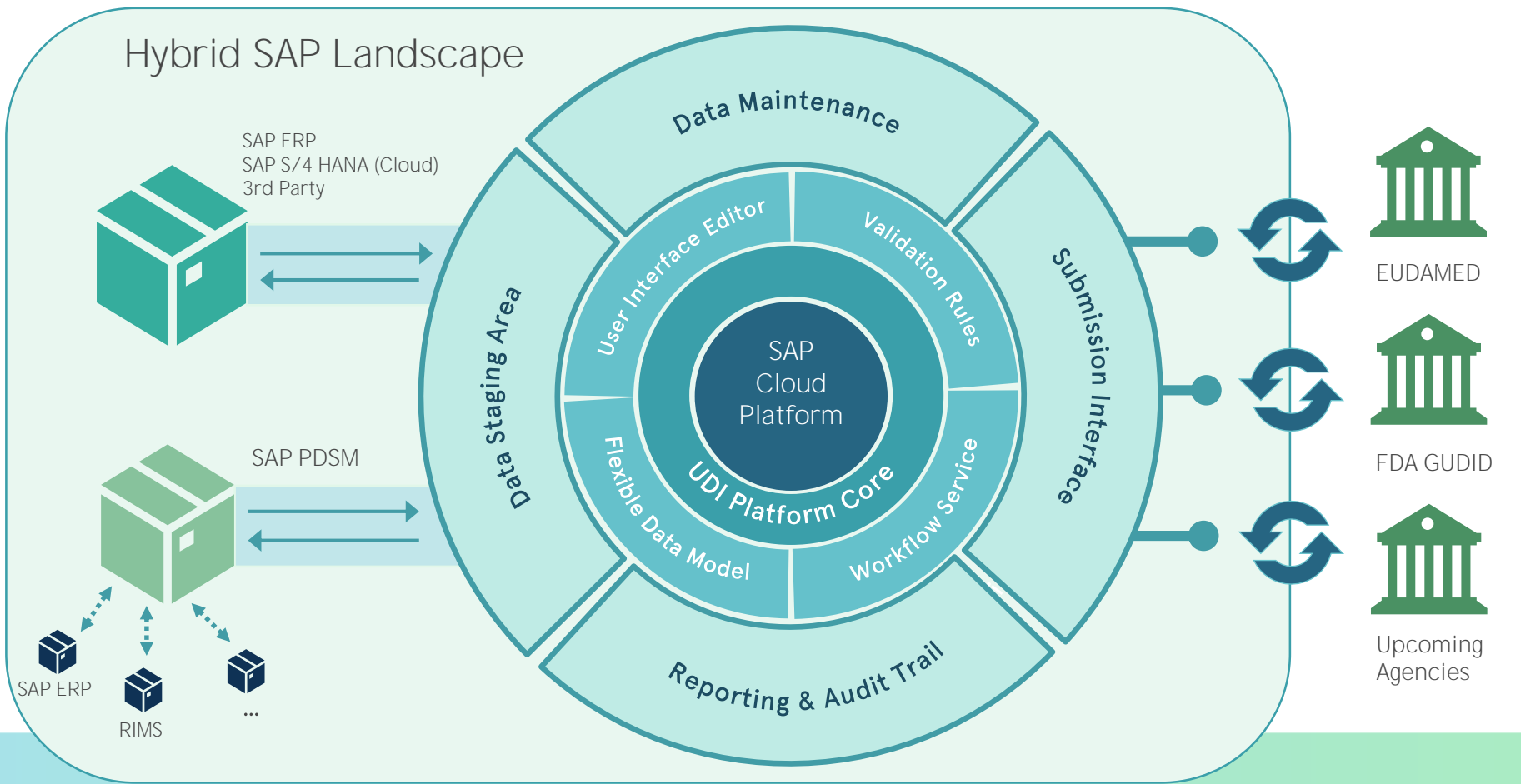
UDI Platform (as a Service)

SAP Cloud Platform

# UDI Platform at a glance



# Hybrid SAP Landscape



# Get a first impression!

Maintain Basic UDI-DI data

Basic UDI-DI 6254231057

Basic UDI-DI Data

Manufacturer SRN: 892439812390  
 Manufacturer: The Demo Company AG  
 Representative: The Representative Demo Company  
 Risk class: Implantable  
 \*Medical device nomenclature: bl  
 \*Reference: Blood screening tool 57569  
 Blood glucose system 57589

Maintain UDI-DI data

Basic UDI-DI 6254231057 Blood screening

UDI-DI Data

UDI-DI: 29472746293619  
 Name: Microscope 100.1  
 Add. Name: Micro 1  
 Product Description: My new Microscope  
 Reference: 920929  
 Unit of use UDI-DI:  
 PI Content:  Expire  Lot  Serial  
 Nomenclature Code: Blood screening tool

Storage:  
 Warnings:  
 Status: On the market  
 URL: google.de  
 Reuse:  
 Manufactured By:  
 Single Use:  NO  YES  
 Sterile:  YES  NO  
 Sterilization:

Container Packages

Data Validation

UDI Requests (8)

Blood screening 6254231057

Diabetes Check 6254231056

Blood screening 6254231057

Heartbeat screening 6254231055

Diabetes Check 6254231056

Blood screening 6254231057

Diabetes Check 6254231056

Task Log

P00032 Submit UDI-DI Request  
 Completed at: 01.11.2018 9:50:54 AM

P00032 Approve Basic UDI-DI Request  
 Completed at: 01.11.2018 9:50:23 AM  
 Step: Maintain UDI-DI data

P00033 UDI-DI Request 6254231057  
 Completed at: 01.11.2018 9:50:19 AM  
 Step: Maintain Basic-UDI-DI data

P00033 UDI-DI Request 6254231057  
 Completed at: 01.11.2018 9:50:19 AM  
 Step: Maintain Basic-UDI-DI data

Status at EUDAMED

Submission [OK] → ACK I [OK] → ACK II [OK] → ACK III [OK]

Submission Status at a glance

UI Editor

Maintain UDI-DI data

SRN: SRN  
 Manufacturer: nameAddressManufacturer  
 Representative: representative  
 Language: language

Risk Class: riskClass  
 Medical device name: mdic  
 Reference Number: referenceNumber

UDI-DI DATA

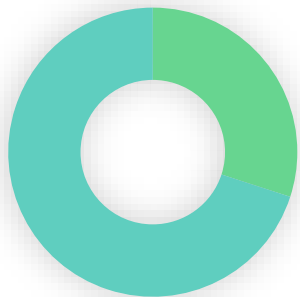
UDI-DI

UDI-DI	udiDi	Storage	storage
Name	name	Warnings	warnings
Additional name	addTraceName	Status	status
Product description	addProductDescr...	URL	url
Reference	referenceNumber	Reuse	maNumberOfRe...
Quantity	quantityPerPacka...	Manufactured By	nameAndAddres...
Unit of use UDI-DI	unitOfUseUDI-DI	Single Use	isSingleUse
PI Content	typesOfPI	Sterile	isSterile
Nomenclature Code	mdic	Sterilization	needSterilization




Flexible Data Models

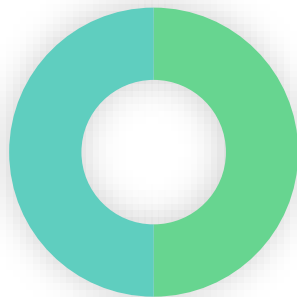
Data Maintenance

# UDI Platform - Adaptable to suit your needs







You already have maintained most of your UDI-Data in your ERP?

-  Validation of your data
-  Simplified Release-Workflow
-  Submission Management








You have your device data ready but no agency specific data?

-  Data enrichment
-  Validation of your data
-  Customized Release-Workflow
-  Submission Management



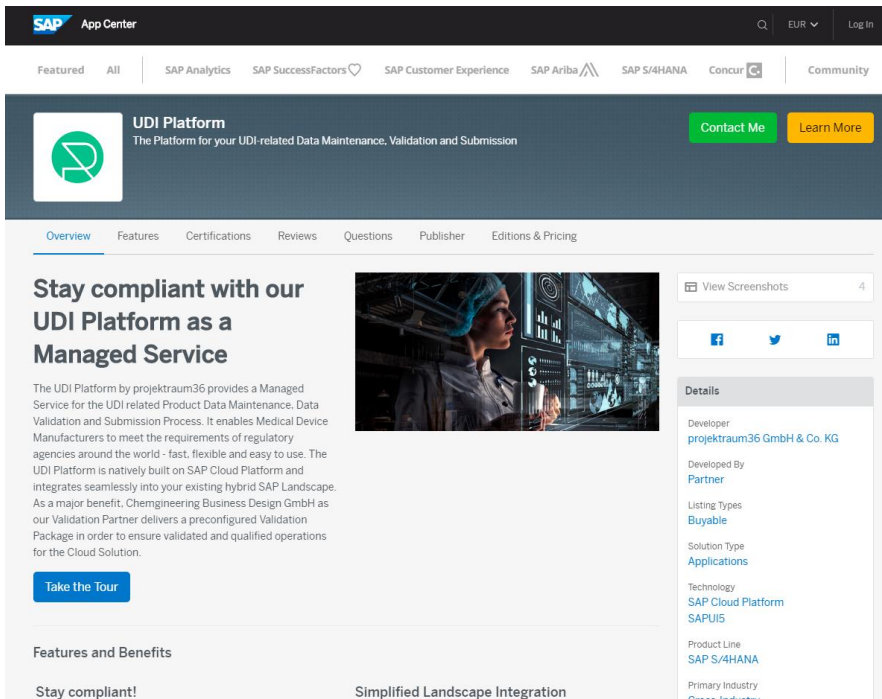
You want to manage most of your UDI-data in the Platform?

-  Create new maintenance flows
-  Data enrichment
-  Validation of your data
-  Customized Release-Workflow
-  Submission Management

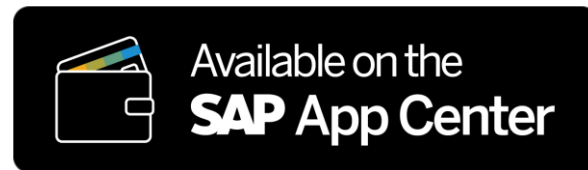
# Integration Options

	SAP ERP	S/4 HANA On-Premise	S/4 HANA Cloud	Other systems
REST	✓	✓		✓
ODATA / CDS	✓	✓	✓	
ODATA	✓	✓		✓
SAP SLT *	✓	✓		
SAP SDI *	✓	✓		✓
SAP PI *	✓	✓		
SAP CPI *	✓	✓		✓

# Visit us in the SAP App Center!



The screenshot shows the SAP App Center interface for the UDI Platform application. At the top, there is a navigation bar with the SAP logo, 'App Center', a search icon, 'EUR', and 'Log In'. Below this is a category menu with 'Featured', 'All', 'SAP Analytics', 'SAP SuccessFactors', 'SAP Customer Experience', 'SAP Ariba', 'SAP S/4HANA', 'Concur', and 'Community'. The main header for the application includes the 'UDI Platform' logo, a description: 'The Platform for your UDI-related Data Maintenance, Validation and Submission', and two buttons: 'Contact Me' and 'Learn More'. A secondary navigation bar contains 'Overview', 'Features', 'Certifications', 'Reviews', 'Questions', 'Publisher', and 'Editions & Pricing'. The main content area features a headline: 'Stay compliant with our UDI Platform as a Managed Service', followed by a paragraph of text and a 'Take the Tour' button. To the right of the text is an image of a person in a lab coat looking at a futuristic data display. Below the text is a 'Features and Benefits' section with the text 'Stay compliant!' and 'Simplified Landscape Integration'. On the right side, there is a 'View Screenshots' section with a dropdown menu showing '4' screenshots, social media icons for Facebook, Twitter, and LinkedIn, and a 'Details' section listing: Developer: projektraum36 GmbH & Co. KG; Developed By: Partner; Listing Types: Buyable; Solution Type: Applications; Technology: SAP Cloud Platform, SAPUI5; Product Line: SAP S/4HANA; Primary Industry: Process Industries.





Thank you for  
your Attention!

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