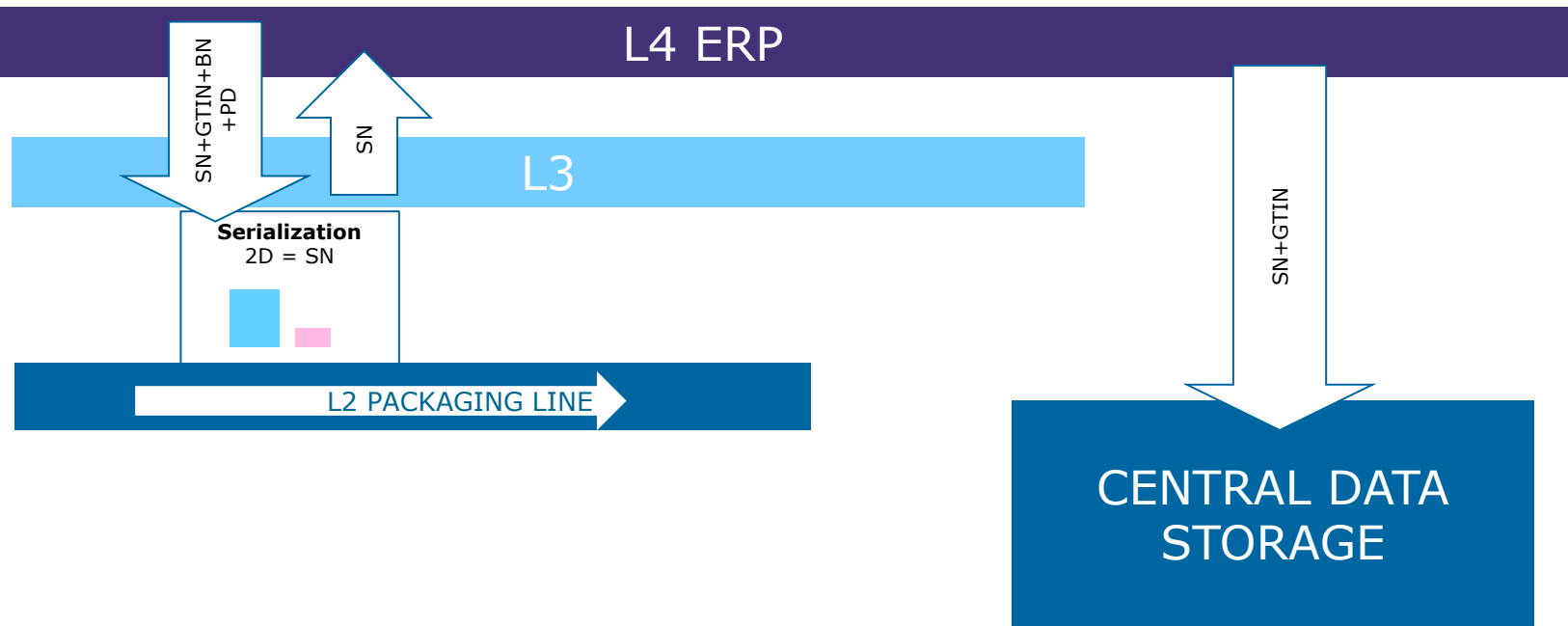


**traceability**  
perfect data + perfect product

# Traceability project in Russia

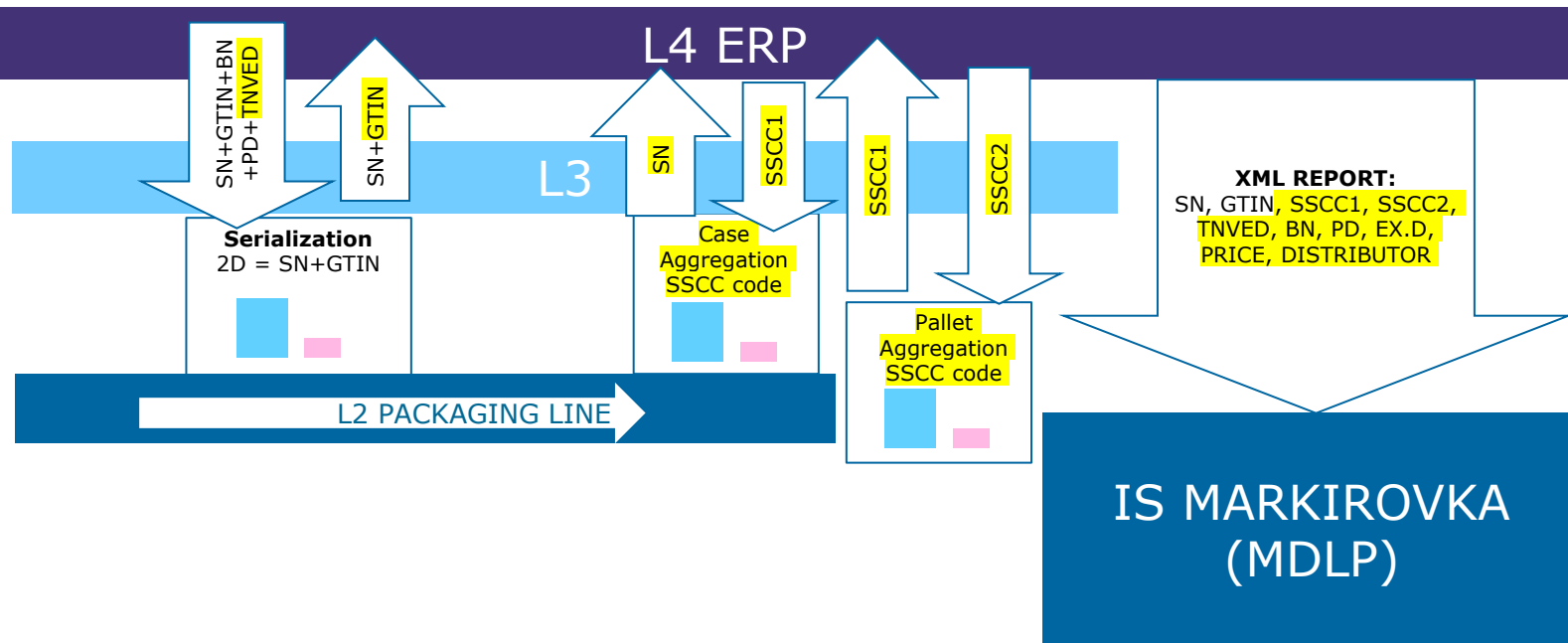
Crypto extension for 2D codes

# Basic solution for EU T&T standard

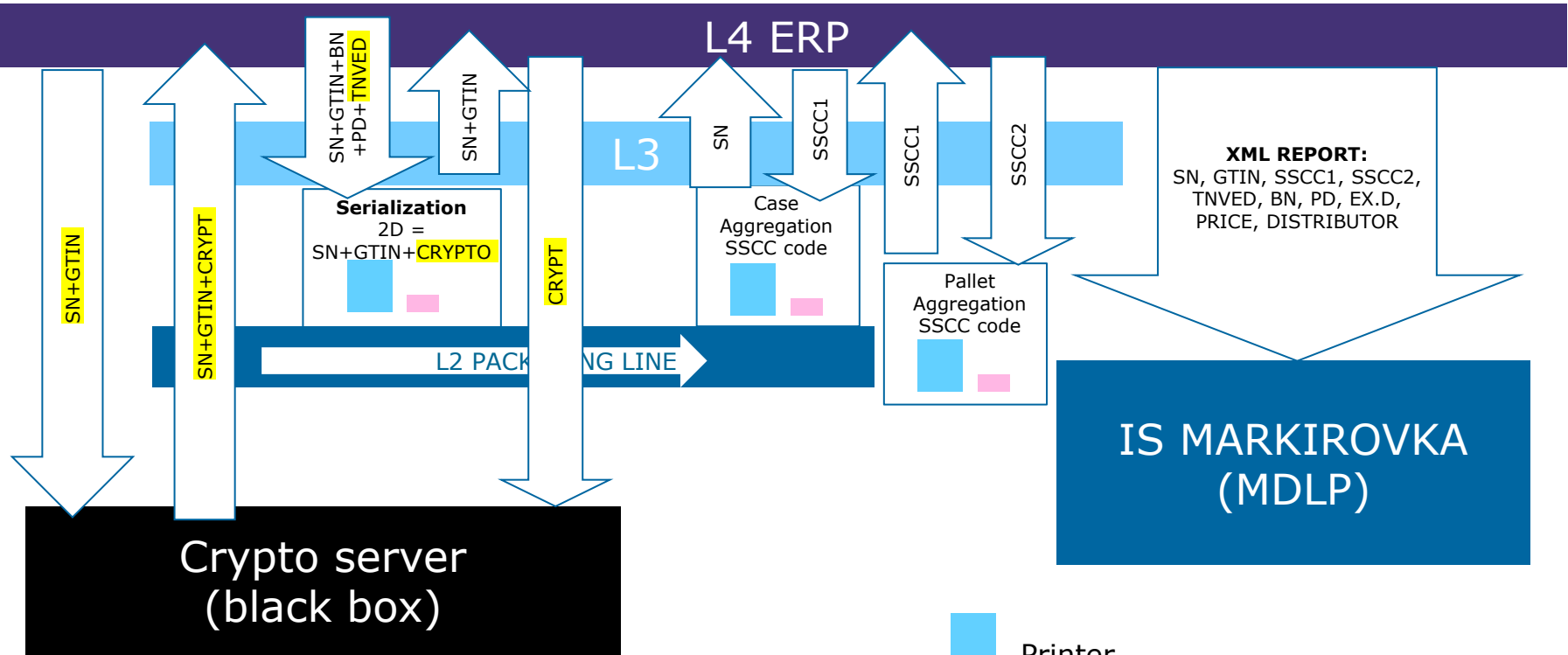


-  Printer
-  Scanner

# Solution based on Methodical Recommendations

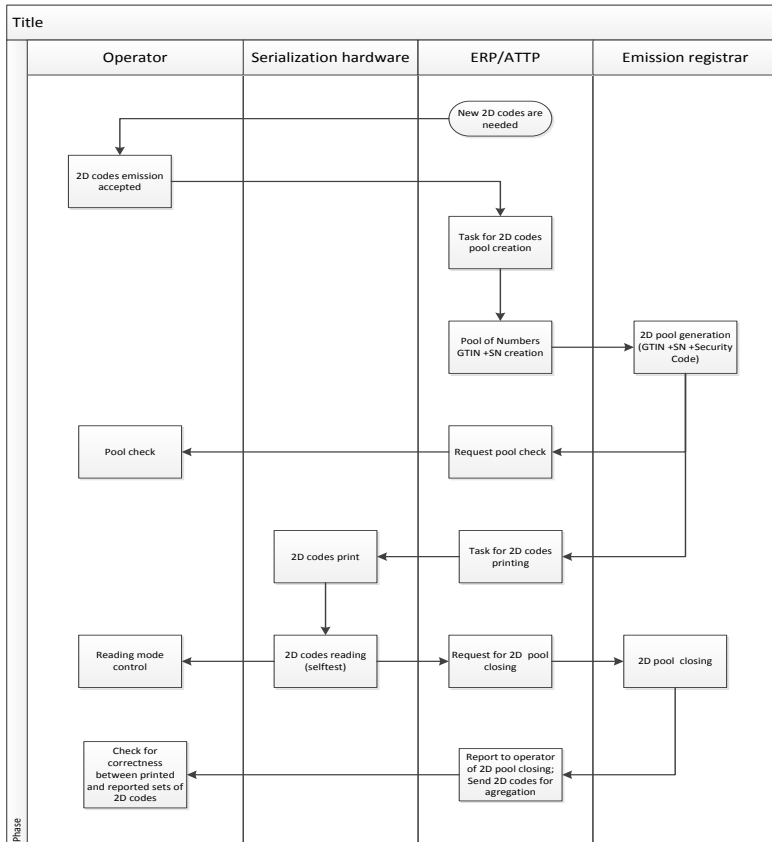


# Integrated solution with implanted crypto server



# Security Code request/response process flow (for domestic manufacturer)

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- ▶ Operator: legal entity acting as operator of State Information System for Security Codes (Center for Advanced Technologies)
- ▶ Emission registrar: local (implanted) crypto server

# Changes in 2D code structure



Field	Num. of chars	Included in AZ 2D matrix code	Included in 2D extended code	Human readable info	Reporting to IS MDLP
(01) GTIN	14	Y	Y	Y	Y
(11) Manufacture date YYMMDD	6	Y/N		Y	
(17) Exp.date YYMMDD	6	Y/N		Y	Y
(10) Batch Number	20	Y/N		Y	Y
(21) Serial Number	13	Y	Y	Y	Y
(240) FEACN (TNVED) Code	4				Y
(91) Verification Key	4		Y		
(92) Digital Signature	88		Y		
<b>Code length (data)</b>		<b>31-57</b>	<b>127</b>		<b>57</b>
<b>Code size</b>		<b>22 x 22</b>	<b>40 x 40</b>		

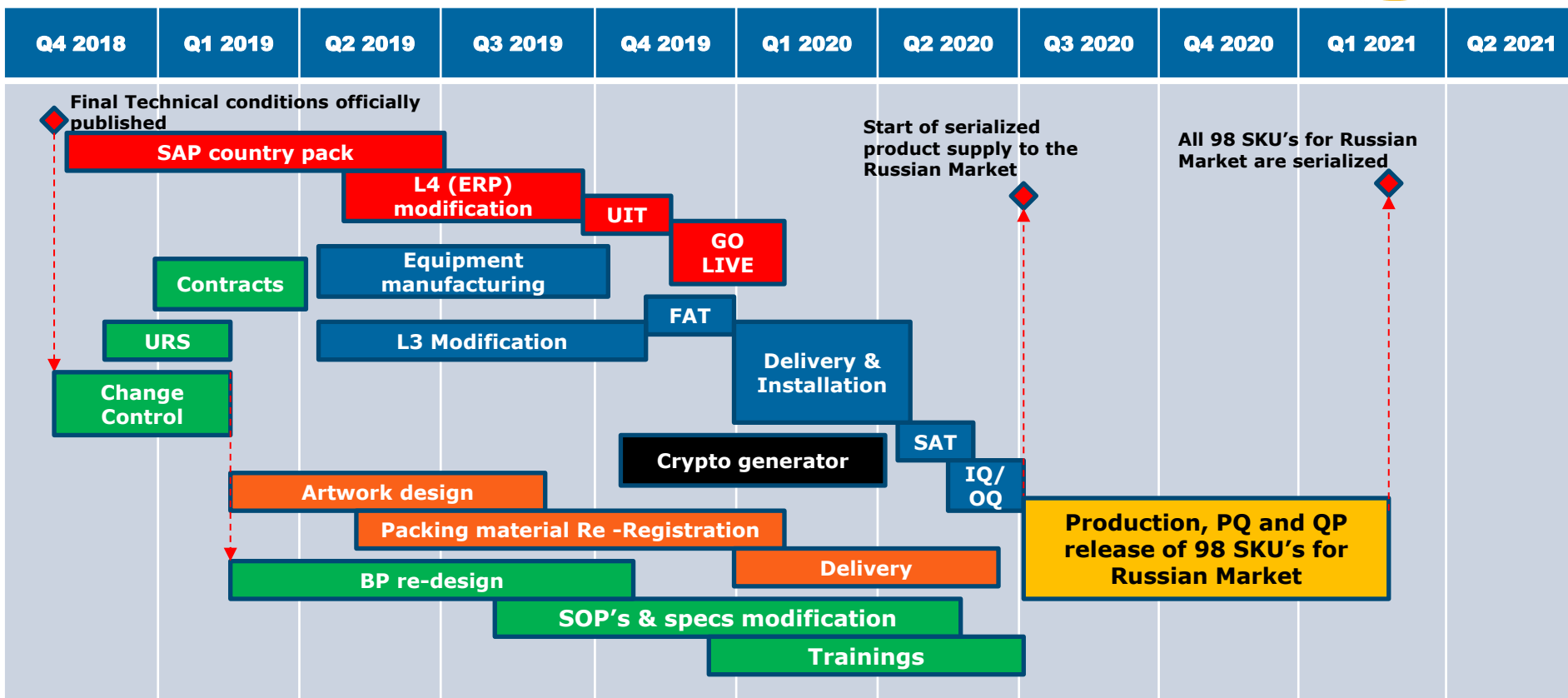


(01)09506000117843  
(17)201231  
(10)1234AB  
(21)5678634802537



(01)09506000117843  
(21)5678634802537  
(91)A1B2  
(92)1234AB325448295672948  
5037820503859375057204004  
TR0385730505729830503036  
040264552834940572

# New schedule (Optimistic scenario)



# Conclusion



- ▶ New crypto-protection requirements will extend project timeline by as minimum as 18 months, realistically – 2 years for big manufacturing companies.
- ▶ Implementation of new requirements will result in additional investments into Software modification and Equipment. Amount of these investments could be in the range of 50K Euro per line or more.
- ▶ Proposed T&T scheme in Russia is the most complex in the world and has no analogs. There is a very high risk that of facing many technical issues during system implementation which may affect medicines availability for patients.



# BACK UP

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# 2D Data Matrix Symbol Requirements

(AZDoc0076901 Product Security Coding Specification Russia 2018)



- ▶ The 2D data matrix is to be printed with a minimum X-dimension of 0.3 mm. The GS1 standard states minimum 0.255 mm, maximum 0.615 mm with a target of 0.3 mm. Larger X-dimensions may be required to facilitate vision system operation.
- ▶ A quiet zone of 1.2 mm shall be provided around the Data Matrix. The GS1 standard recommends a quiet zone width equal to the X dimension as a minimum.
- ▶ The Data Matrix must use the ECC200 compliant data carrier structure and attributes must be encoded using the GS1 standard.
- ▶ The characters encoded must conform to the ISO/IEC 646 character set (ASCII 256).
- ▶ The number of rows and columns of the Data Matrix is determined by the amount of data encoded. The GS1 standard provides guidance on matrix sizes, although this is normally automatically determined by the printer
- ▶ See [GS1 DataMatrix Guideline](#)

# Crypto extension for 2D codes for goods labeling: legal status



- ▶ Government directives #791 and #792
- ▶ Draft decree of the Government of the Russian Federation on T&T system operator issued
- ▶ Government directive #1018 «On Approval of the Regulation of the Monitoring System»

# Features of printing GS1 Data Matrix (Inkjet printing, 127 characters or more)



Code size (in modules)	Module size * (mm)	GS1 requirements **	Code size (mm)	One-pass printing	Print quality
36X36	0.423	YES	15.23 x 15.23	NO ***	
	0.339	NO	12.2 x 12.2	NO ***	
	0.254	NO	9.14 x 9.14	YES	Poor print quality (F) <ul style="list-style-type: none"> <li>• High level of rejection on the line</li> <li>• High probability of claims from the market</li> </ul>
40 X 40	0.423	YES	16.92 x 16.92	NO ***	
	0.339	NO	13.56 x 13.56	NO ***	
	0.254	NO	10.16 x 10.16	YES	Poor print quality (F) <ul style="list-style-type: none"> <li>• High level of rejection on the line</li> <li>• High probability of claims from the market</li> </ul>

\* For inkjet printing, it is not possible to set intermediate values between 0.254, 0.339 and 0.423 mm

\*\* According to the General Specification GS1, module size is 0.396 mm min

\*\*\* For the print head of the inkjet printer, matrix height is 12 mm max

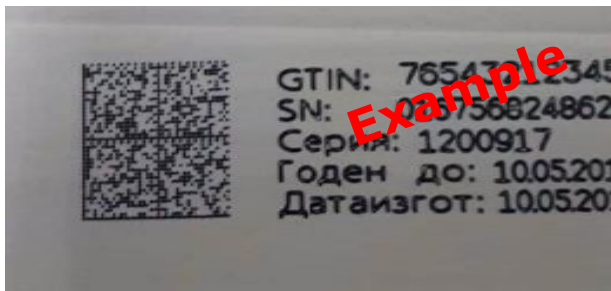
# Takeda 2D code print/read test

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- ▶ Module size: 251 $\mu$ m
- ▶ Matrix size: 48x48
- ▶ Matrix dimensions: 12x12mm
- ▶ Total codewords: 242
- ▶ Data codewords: 174
- ▶ Check codewords: 68
- ▶ Code content (HR):  
(01)04055724000078(21)RskACLUOUTU5X(91)1234(92)Vcyp7D/dT9BUVqaDKCrRkK8bRJ8YvDUU+s8KT  
XU5v/MIJNIne5mtsoopmDR2KRKugqim3xI/IKbmThky0XZZLw==
- ▶ Results:
  - **Test failed due to high density of printed data**



Adobe Acrobat  
Document



#### List of errors:

- 01) Fixed pattern damage too high.
- 02) Modulation value too low.
- 03) Module size too low, actual: 251 $\mu$ m, min: 254 $\mu$ m.
- 04) Reflectance margin too low.
- 05) Value of Unused Error Correction (UEC) too low, actual: 0%, min: 37%.

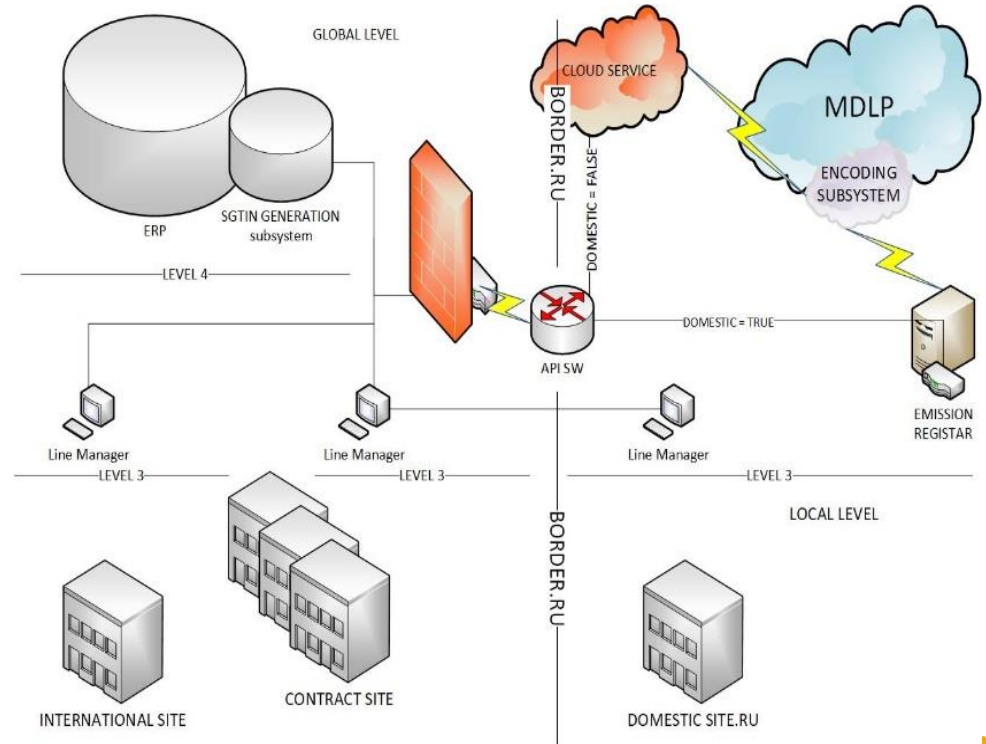
#### Barcode Verification Report

test\_2018-09-04\_#006.tws

AstraZeneca

# High level diagram of communication with operator

- ▶ Security Code For Importers will be obtained via cloud service
- ▶ Security Code for domestic manufacturers (every plant resides in Russia Federation) must be generated by server (Emission registrar) physically located on site.
  - Important: this server wouldn't be included in company's LAN.
- ▶ JSON HTTP protocol is used for Security codes request.



# Next steps



- ▶ Testing of printing and scanning of 2D codes with crypto extension on existing equipment at Vorsino (physical size HxW of 17x17mm or 10x30mm )
- ▶ Communication with AIPM and legal authorities (incl. Center for Advanced Technologies) to align understanding of technical requirements and workflow
- ▶ Monitoring the legal status of the subject