European Medicines Verification Organisation (EMVO)  
MAH On-boarding

Tobias Beer  
(Head of Commercial & Partner Management)

www.emvo-medicines.eu  
helpdesk@emvo-medicines.eu
Agenda

- General Information
- How to get connected?
- Overview 32 participating Countries
- Status per Country
FMD Legislation and Delegated Act

- **Connect approx. 2,500 pharmaceutical companies to the EU Hub**
- Connect 32 National Systems
- Connect many thousand Pharmacies and Wholesalers to the NMVS
- Serialise all affected pharmaceutical packs (10.5 bn)

2011

*July 2011*  
Publication of FMD

2016

*9 Feb 2016*  
Publication of Delegated Regulation

2017

2018

2019

*9 Feb 2019*  
Mandatory verification of all packs in scope

~ 600 days remain


FMD: Falsified Medicines Directive

15 June 2017

Tobias Beer (EMVO)
Organisational chart

EMVO Board of Directors
President: Hugh Pullen (EFPIA)
Vice-President: Sonia Ruiz Morán (PGEU)
Treasurer: Richard Freudenberg (EAEPC)
Monika Derecque-Pois (GIRP)
Adrian van den Hoven (Medicines for Europe)

General Manager
Andreas Walter

Head of Commercial & Partner Management
Tobias Beer

Operations
Paul Mills

Office Manager
Marisa Jimenez Sanchez

Quality Assurance
Stephan Theunissen

Support Center

Christoph Krähenbühl
(external consultant)

Markus Gerigk
(external consultant)

André Geraldes
Fanny Trenteseaux
NN
Willem Theunissen

15 June 2017
Tobias Beer (EMVO)
Agenda

1. General Information
2. How to get connected?
3. Overview 32 participating Countries
4. Status per Country
OBP: On-boarding Partner
NMVS: National Medicines Verification System
NMVO: National Medicines Verification Organisation
What is an “OBP”? 

- OBP means On-Boarding Partner and is the contracting party of EMVO and concludes the non-disclosure agreement (NDA) and participation agreement (PA).
- The OBP is legally authorized to sign on behalf of a MAH/a group of MAHs.
- The OBP has to be affiliated (*) to a MAH/a group of MAHs.

(*) Affiliate shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).
Relationship OBP* and EMVO

Corporation/Group

OBP*

OBP’s System

EMVO

EU Hub

Participation Agreement

Sends Data to the HUB

Affiliated entity “Producer 1”

Affiliated entity “Marketing Authorisation Holder A”

Affiliated entity “Marketing Authorisation Holder B”

“Affiliated entity Marketing Authorisation Holder C”

Affiliated entity “Producer 2”

Affiliated entity “Sales Rep. 1”

Affiliated entity “Sales Rep. 2”

Contract Manufacturing Organisation

*On-Boarding Partner

*Confirmation letter

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Relationship OBP* and EMVO

**Corporation/Group**

- Affiliated entity “Marketing Authorisation Holder A”
- Affiliated entity “Marketing Authorisation Holder B”
- "Affiliated entity Marketing Authorisation Holder C”
- Affiliated entity “Producer 1”
- Affiliated entity “Producer 2”
- Affiliated entity “Sales Rep. 1”
- Affiliated entity “Sales Rep. 2”

**OBP’s System**

- Sends Data to the HUB

**EMVO**

- EU Hub

**Contract Manufacturing Organisation**

- *On-Boarding Partner
- *Confirmation letter

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Tobias Beer (EMVO)
Prerequisite to on-board
> 2,500 MAHs/Parallel Distributors

User-friendly web-based portal

Decrease EMVO's response time

Starting point/trigger for legitimacy check
Welcome to EMVO's On-boarding Partner Portal

In order to continue, you will need a valid email address. Once you complete the registration form, we'll send you an invitation email with instructions and next steps.

Request to participate >

https://www.emvo-medicines.eu/eu-hub-on-boarding/obp-portal/
How to request to participate

1. Via website – link

2. Fill in User + Company details

3. You’ll be directed to the confirmation screen

4. Check your email to validate your account

Please check your junk email / spam
How to request to participate

5. Your company portal will be created

6. Your company portal is created

7. Follow the instructions in your email to login to your Company portal

Please check your junk email / spam

8. Your Company portal is ready to On board

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On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding
### Step 1: Provide Initial Information

**Trigger step 1:** Successful Request to Participate

<table>
<thead>
<tr>
<th>Step 1: Provide initial information</th>
<th>Time to complete</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Company information</td>
<td>Add 5-7 min</td>
<td>Not Started</td>
</tr>
<tr>
<td>1.2 Authorised representative information</td>
<td>Add 5-7 min</td>
<td>Not Started</td>
</tr>
<tr>
<td>1.3 Pre-technical Connection Information</td>
<td>Add 5-7 min</td>
<td></td>
</tr>
</tbody>
</table>

**To add or modify the requested information**

**Estimated time to complete**

**Status:**
- Not Started
- In Progress
- Complete
Please provide all the necessary/mandatory information of your Company which will be used for the legitimacy check.

Company Information

- Company Name: EMVO
- Country of Registration: Belgium
- VAT Number: 11111111111
- Company Registration Number: 
- Street: 
- Number: 
- Box: 
- Zip code: 
- City: 
- Country: 
- Business Phone: 
- Web Page: 
- Company Email Address: 
- Are you part of a corporation? 
- Do you represent?  
  - Marketing Authorisation Holders (MAH) with Parallel Distribution activity
  - Marketing Authorisation Holders (MAH) without Parallel Distribution activity

Save  Cancel
1.2 Authorised Representative

Please provide all the necessary/mandatory information of the Authorised representative which will be used for the legitimacy check.

<table>
<thead>
<tr>
<th>Authorised representative information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name *</td>
</tr>
<tr>
<td>Last Name *</td>
</tr>
<tr>
<td>Job Title *</td>
</tr>
<tr>
<td>E-Mail *</td>
</tr>
<tr>
<td>Business Phone *</td>
</tr>
</tbody>
</table>

I confirm that I've uploaded an attachment which proves the authorized representative is entitled to sign on behalf of the company *

Copy of Proof Attach file

---

**Note:**
The Authorised Representative will be the person who need to sign the Participation Agreement and the Non-Disclosure Agreement.

---

**Trade register excerpt from Bulgaria**

**Obligated** for the legitimacy check

**Action:**
A prefilled NDA will be generated
1.3 Connection Provider Information

Optional:
This field can be used to provide us info concerning the desired
Connection to the EU Hub (if already known at this stage)

Pre-technical Connection Information

- Direct Connection
- Gateway Provider
  - EMVO Gateway

List with Certified * Gateway Providers which allows the OBP to start immediately the mini-certification test in the Integrated Quality Environment (IQE)

Note:
We only allow 2 connection per OBP

* Certified Gateway Provider is a provider which for a first OBP already passed the full certification test of the Gateway of this Gateway Provider

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### OBP Connection Providers

<table>
<thead>
<tr>
<th>Connection Type</th>
<th>OBP CP</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct</td>
<td>SAP SE</td>
<td>Registered</td>
</tr>
<tr>
<td>Gateway</td>
<td>EMVO Gateway</td>
<td>Certified</td>
</tr>
<tr>
<td>Gateway</td>
<td>TraceLink, Inc.</td>
<td>Certified</td>
</tr>
<tr>
<td>Gateway</td>
<td>Adents High Tech International</td>
<td>Registered</td>
</tr>
<tr>
<td>Gateway</td>
<td>Arvato systems GmbH</td>
<td>Registered</td>
</tr>
<tr>
<td>Gateway</td>
<td>Tracekey Solutions GmbH</td>
<td>Sponsored</td>
</tr>
<tr>
<td>Gateway</td>
<td>Antares Vision s.r.l.</td>
<td>Sponsored</td>
</tr>
<tr>
<td>Gateway</td>
<td>Axway</td>
<td>Sponsored</td>
</tr>
<tr>
<td>Gateway</td>
<td>Advanco</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>Seeberger BIS Software</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>rfXcel</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>BRAINORITY Software GmbH</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>Giesecke &amp; Devrient GmbH</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>SecuriKett Ulrich &amp; Horn GmbH</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>Optel Group</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>ACG Inspection Systems Pvt Ltd.</td>
<td>Candidate</td>
</tr>
<tr>
<td>Gateway</td>
<td>Verifarma</td>
<td>Candidate</td>
</tr>
</tbody>
</table>


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Tobias Beer (EMVO)
On-Boarding Partner Portal

1. Step 1: Provide Initial Information
2. Step 2: Non-Disclosure Agreement
3. Step 3: Participation Agreement + Detailed information
4. Step 4: Approvals
5. Step 5: Technical On Boarding
Step 2: Non-Disclosure Agreement

Trigger step 2:
- Company information available
- Authorised Representative Information available

Status:
Not Started
Available

Status:
Not Started
Awaiting Approval
Approved
Rejected

Status:
No Status
Awaiting hardcopy
Send back on xx:xx:xxxx
On-Boarding Partner Portal

Step 1: Provide Initial Information

Step 2: Non-Disclosure Agreement

Step 3: Participation Agreement + Detailed information

Step 4: Approvals

Step 5: Technical On Boarding

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Step 3: Detailed information and Participation Agreement

View and Download prefilled Participation Agreement

Upload signed Participation Agreement

<table>
<thead>
<tr>
<th>Step 3: Detailed information and participation agreement</th>
<th>Time to complete</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 General info pack</td>
<td>Open</td>
<td>Available</td>
</tr>
<tr>
<td>3.2 Single point of contact information</td>
<td>Modify</td>
<td>Complete</td>
</tr>
<tr>
<td>3.3 Participation Agreement</td>
<td>View Download</td>
<td>Available</td>
</tr>
<tr>
<td>3.4 Upload Signed Participation Agreement</td>
<td>Upload PDF</td>
<td>Awaiting approval</td>
</tr>
<tr>
<td>3.5 Invoicing information</td>
<td>Add</td>
<td>Not Started</td>
</tr>
<tr>
<td>3.6 Additional company information</td>
<td>Add</td>
<td>Not started</td>
</tr>
<tr>
<td>3.7 MAH and product information</td>
<td>Add</td>
<td>Not started</td>
</tr>
</tbody>
</table>

Step 4: Approvals

Step 5: Technical onboarding

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Tobias Beer (EMVO)
OBP Contracts with EMVO

1. Non-Disclosure Agreement (NDA)
   - Covers **provision of Confidential Information** by EMVO, e.g. on
     - European Hub
     - Gateway
     - SDK
   - Purpose: **Assessment of participation** in the EMVS project

2. Participation Agreement (PA)
   - Contractual framework for participation in the On-boarding project, e.g.
     - Use of Gateway
     - Interface development
     - Connect to the HUB
   - Purpose: **Execution of Technical On-Boarding**
OBP Contracts with EMVO

1. Non-Disclosure Agreement (NDA)
   - Covers provision of Confidential Information by EMVO, e.g. on European Hub, Gateway, SDK
   - Purpose: Assessment of participation in the EMVS project

2. Participation Agreement (PA)
   - Contractual framework for participation in the On-boarding project, e.g. Use of Gateway, Interface development, Connect to the HUB
   - Purpose: Execution of Technical On-boarding

No Contract Negotiation
3.2 Single point of contact

Please provide all the necessary/mandatory **information of the Single point of contact** which will be used to generate the Participation Agreement

<table>
<thead>
<tr>
<th>Single Point of Contact</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>SPOC First Name *</td>
<td></td>
</tr>
<tr>
<td>SPOC Last Name *</td>
<td></td>
</tr>
<tr>
<td>SPOC Email Address *</td>
<td></td>
</tr>
<tr>
<td>SPOC Phone Number *</td>
<td></td>
</tr>
<tr>
<td>SPOC Availability Hours *</td>
<td>Monday to Friday 09:00 to 16:00 CET</td>
</tr>
<tr>
<td>SPOC First Name</td>
<td></td>
</tr>
<tr>
<td>SPOC Last Name</td>
<td></td>
</tr>
<tr>
<td>SPOC Email Address</td>
<td></td>
</tr>
<tr>
<td>SPOC Phone Number</td>
<td></td>
</tr>
<tr>
<td>SPOC Availability Hours</td>
<td></td>
</tr>
</tbody>
</table>

**Note:**
The Single point of contact will be confirmed by the Authorized Representative in the Participation Agreement to be the responsible for providing all the required information in the OBP Portal for the On-boarding of the OBP

**Action:**
A prefilled Participation Agreement will be generated
3.5 Invoicing information

Please provide all the necessary/mandatory invoicing information to where we can address the Invoicing form.

Invoicing information

Street *

Number *

Box

Zip code *

City *

Country *

Business Phone *

Company Email Address *

Save  Cancel
## One-Time Fee per OBP

| OBPs with more than 12 MAHs in Europe | 20,000 € |
| OBPs with 6 to 12 MAHs in Europe      | 10,000 € |
| OBPs with 3 to 5 MAHs in Europe       | 8,000 €  |
| OBPs with 2 MAHs in Europe            | 6,000 €  |
| OBPs with 1 MAH in Europe             | 3,000 €  |
On-Boarding Partner Portal

1. Provide Initial Information
2. Non-Disclosure Agreement
3. Participation Agreement + Detailed information
4. Approvals
5. Technical On Boarding
Step 4: Approvals

Trigger step 4:
• Step 3 completed

Step 1: Provide initial information
Status: Complete

Step 2: Non-disclosure agreement
Status: Complete

Step 3: Detailed information and participation agreement

Step 4: Approvals

- 4.1 Legitimacy check status
  Status: 14 days
- 4.2 Countersigned Participation Agreement send back to OBP
  Status: 21 days
- 4.3 Invoice status

Status:
Not Started
Awaiting harcopy
Sent back on xx:xx:xxxx

Status:
Not Started
Awaiting payment
Payment received

15 June 2017
Tobias Beer (EMVO)
Technical On-boarding

- Starts when Participation Agreement is signed by EMVO

- OBP will connect his client sequentially to:
  - the ITE environment to develop an interface
  - the IQE environment to certify his interface
  - The PRD environment to use his interface

- OBP can choose to connect via
  - a Direct connection (data send from client straight to EU Hub)
  - a Gateway connection (Data sent first to a Gateway Provider. The Gateway Provider sends it through to the EU Hub
EU Hub Environments

ITE environment
- Integrated Test Environment
- Used as sandbox by multiple OBP’s
- Integration testing of OBP’s connection

IQE environment
- Integrated Quality Environment
- Used for Quality- & Certification testing by multiple OBP’s
- Validated environment

PRD environment
- Productive Environment
- Validated environment

ITE: Integrated Test Environment
IQE: Integration Quality Environment
PRD: Productive Environment
THANK YOU for your ATTENTION!
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Blueprint Tendency

- **Yes**: Stakeholder agreed to go for Blueprint
- **SCB**: Small Country probably connecting to Blueprint
- **No**: Stakeholder decided against Blueprint
- **Open**: Stakeholder are still in discussion about approach
- **Rest**: Not enough information about approach yet

The chart shows the trend of stakeholder decisions from May 2016 to April 2017, with data collected as of 15 June 2017 by Tobias Beer (EMVO).
Technical Work Stream

- Project Manager established
- Contact to the IT service providers established
- IT service provider selected
- Contract with IT service provider signed

15 June 2017
Tobias Beer (EMVO)
Agenda

General Information

How to get connected?

Overview 32 participating Countries

Status per Country
## Status per Country 1-8

### Governance

<table>
<thead>
<tr>
<th></th>
<th>Austria</th>
<th>Belgium</th>
<th>Bulgaria</th>
<th>Croatia</th>
<th>Cyprus</th>
<th>Czech Republic</th>
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<th>Estonia</th>
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<tbody>
<tr>
<td>1</td>
<td>Align</td>
<td>MoU</td>
<td>Stat</td>
<td>NMVO</td>
<td>PM</td>
<td>ProvC</td>
<td>ProvS</td>
<td>Contr</td>
</tr>
<tr>
<td>2</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

- **Align**: Green indicates alignment, white indicates no alignment.
- **MoU**, **Stat**, **NMVO**: Similar indicators as above.
- **PM**, **ProvC**, **ProvS**, **Contr**: Similar indicators as above.

### Technical

- **B**: Green indicates active participation, red indicates inactive participation.
- **R**: Yellow indicates incomplete stakeholder participation.

= Change in last month  
= Incomplete Stakeholder Participation

15 June 2017  
Tobias Beer (EMVO)
### Status per Country 9-16

<table>
<thead>
<tr>
<th></th>
<th>Governance</th>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Align</td>
<td>MoU</td>
<td>Stat</td>
</tr>
<tr>
<td>9</td>
<td>Finland</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>France</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Germany</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Greece</td>
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<tr>
<td>13</td>
<td>Hungary</td>
<td></td>
</tr>
<tr>
<td>14</td>
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<td>15</td>
<td>Ireland</td>
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<td>16</td>
<td>Italy</td>
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</tr>
</tbody>
</table>

- **Governance**
  - Change in last month: 
  - Incomplete Stakeholder Participation: 

15 June 2017

Tobias Beer (EMVO)
<table>
<thead>
<tr>
<th>Number</th>
<th>Country</th>
<th>Governance</th>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>Latvia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Liechtenstein</td>
<td>*part of</td>
<td></td>
</tr>
<tr>
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<td>Lithuania</td>
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<td></td>
</tr>
<tr>
<td>20</td>
<td>Luxembourg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Malta</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Netherlands</td>
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<td>23</td>
<td>Norway</td>
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<td></td>
</tr>
<tr>
<td>24</td>
<td>Poland</td>
<td></td>
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</tr>
</tbody>
</table>

Governance: Align, MoU, Stat, NMVO
Technical: PM, ProvC, ProvS, Contr

*B = Change in last month
R = Incomplete Stakeholder Participation

15 June 2017
Tobias Beer (EMVO)
Status per Country 25-32

Governance

<p>| | | | |</p>
<table>
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<tr>
<td>26</td>
<td>Romania</td>
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<tr>
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<td>Slovakia</td>
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<td>28</td>
<td>Slovenia</td>
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</tr>
<tr>
<td>29</td>
<td>Spain</td>
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<tr>
<td>30</td>
<td>Sweden</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Switzerland *</td>
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<td></td>
</tr>
<tr>
<td>32</td>
<td>United Kingdom</td>
<td></td>
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</tbody>
</table>

Technical

<p>| | | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

*participating outside FMD

15 June 2017
Tobias Beer (EMVO)
Executive Summary
Country Readiness

Early Adopter
Main Stream
Late Follower
No Information
Non EU Countries

15 June 2017
Tobias Beer (EMVO)
Already founded NMVOs (I)

Austria
Austrian Medicines Verification Organisation (AMVO)

Helga Tilbes
office@amvo-medicines.at

Belgium
Belgian Medicines Verification Organisation (BEMVO)

Jean-Pierre Engels
info@bemvo.be
www.bemvo.be

Bulgaria
Bulgarian Medicines Verification Organisation (BgMVO)

Iliana Paunova
office@bgmvo.org
www.bgmvo.org

Croatia

Maja Draskovic
Maja.draskovic@bayer.com

Czech Republic

Jakub Tesař
femd@afzp.cz
http://cemvo.cz/

Denmark
Dansk Medicin Verifikation Organisation (DMVO)

Lars Tanderup
info@dmvo.dk
www.dmvo.dk

https://www.emvo-medicines.eu/eu-hub-on-boarding/national-medicines-verification-organisations/
Already founded NMVOs (II)

Estonia
REKS
- Mart Leivo
  - Mart.Leivo@reks.ee

Finland
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