



Software Is Our Business
Sustainability Is Our Passion

Simplify your Data Sharing

An online marketplace that
accelerates study and dossier
sharing

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Chemical Watch Expo 2023



Agenda

- 1 **Intro Questionnaire and Legal Background**
- 2 Conventional Data Sharing Process
- 3 Simplified Data Sharing Process
- 4 Case Study - LoA Market
- 5 Summary

Menti Questionnaire



- Go to menti.com
- Enter code **4587 3946**
- Or scan the QR code

Legal Background – REACH & Data Sharing

Registration, Evaluation, Authorisation and Restriction of Chemicals – REACH...

...improving chemical safety, fostering competitiveness of EU chemical industry, and reducing animal testing while focusing on human health and the environment.

Data Sharing & Joint Submission in context of REACH:

- Multiple entities that register the same substance must follow the principal “one substance, one registration”
- Legal obligation to share data and to organize themselves for joint submission

Key Principles for Data Sharing:

- Make every effort to reach an agreement on sharing of data
- Ensure costs are determined in a “*fair, transparent, and non-discriminatory*” way
- Not for profit

REACH in a Global Context

Examples of upcoming Deadlines

Türkiye KKDIK:

- Dec 31st 2023: >1t / year

Korea K-REACH:

- Dec 31st 2024: 100 - 1000t / year
- Dec 31st 2027: 10 – 100t / year
- Dec 31st 2030: 1-10t / year

Taiwan TCCSCA:

- Dec 31st 2024 or 2025: >1t / year for prioritized (PEC) substances (depending on phase 1 registration), further PECs lists with further deadlines planned

Great Britain UK-REACH

- Oct 27th 2023: >1000t / year
- Oct 27th 2025: 100-1000t / year
- Oct 27th 2027: >1t / year
- Likely to be shifted by 3 years; parliament approval outstanding

Global adoption of
REACH-like legislations



Data Sharing on a
Global Scale

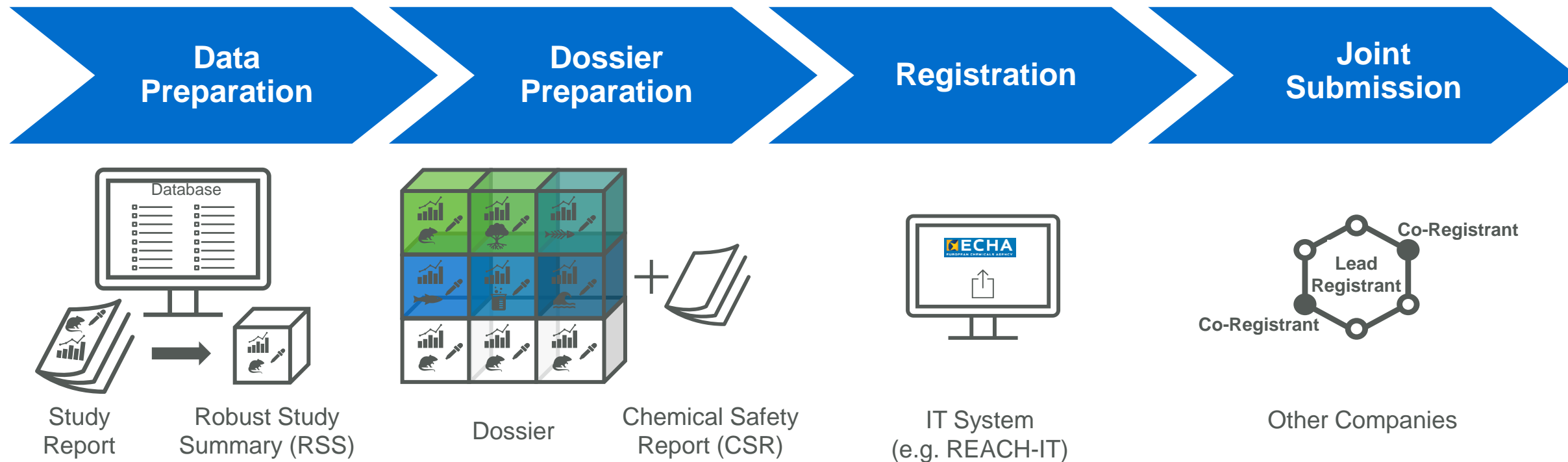
Usual basis for
registration is
EU-REACH

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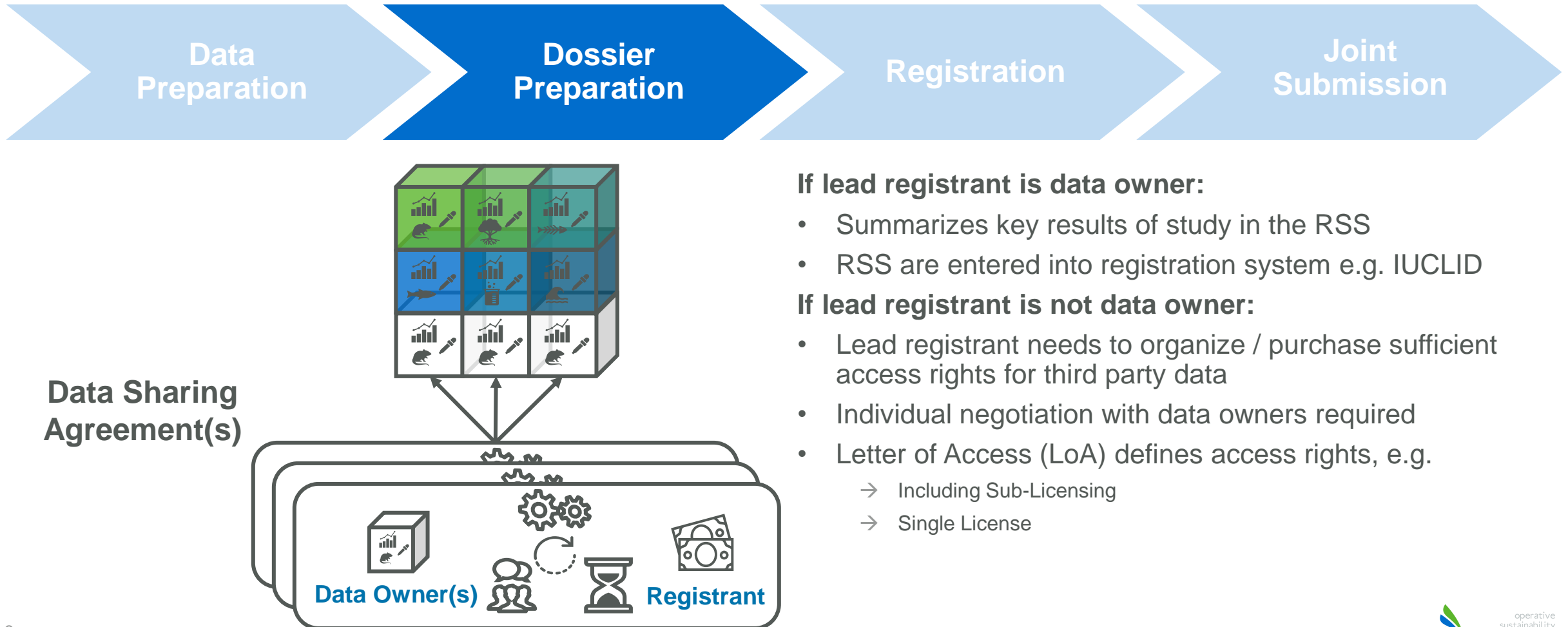
Overall REACH Registration Process*

REACH Registration Process involves many documents, systems and stakeholders



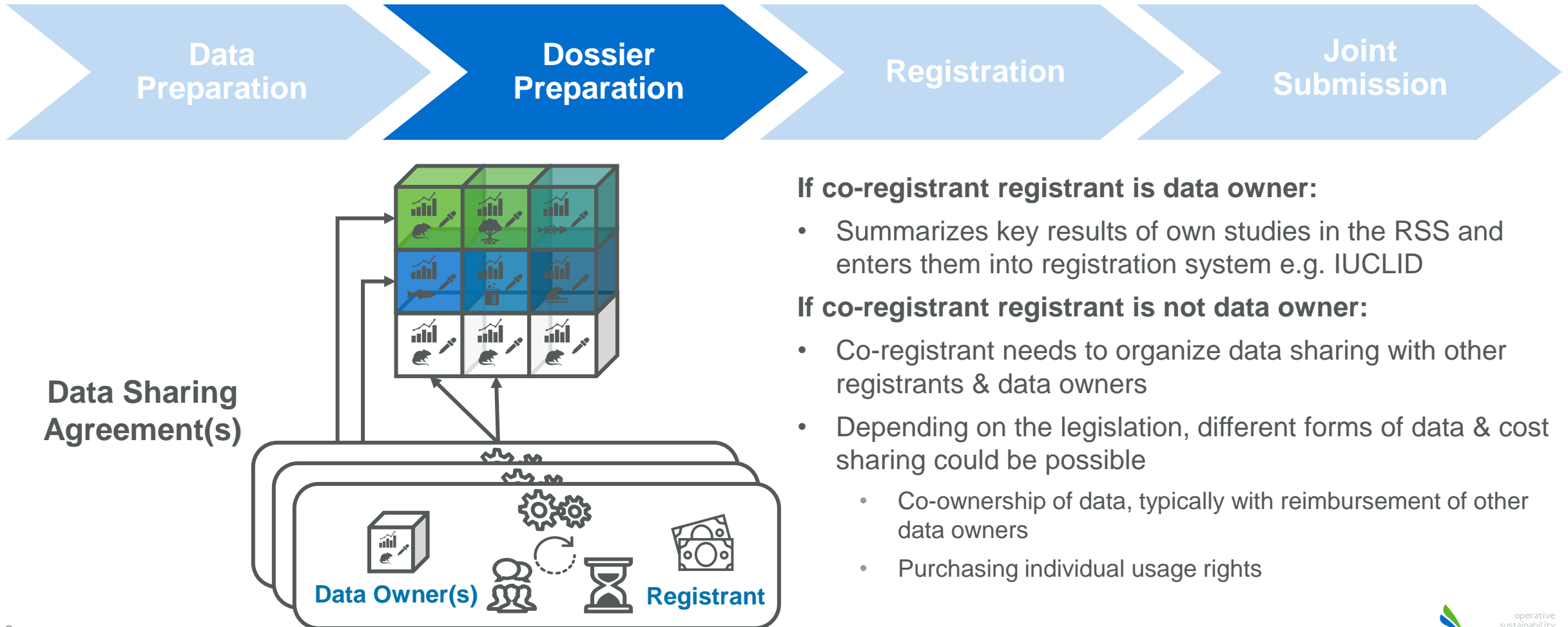
Registration Process – Dossier Preparation as Lead Registrant

Lead registrant needs to ensure data access from other data owners



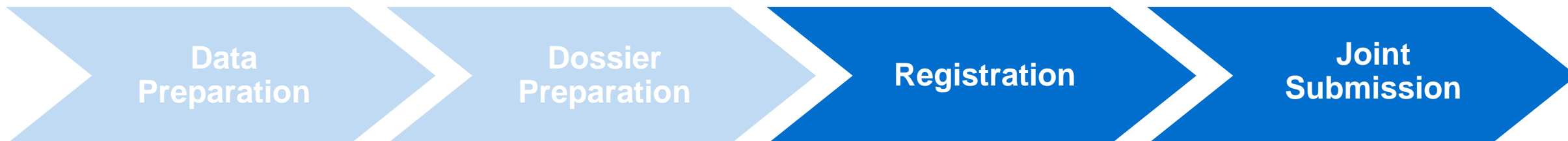
Registration Process – Dossier Preparation as Co-Registrant

Co-registrant needs to ensure data access from other registrants & data owners



Registration Process – Registration and Joint Submission

Lead and co-registrant(s) are obliged to form a joint submission

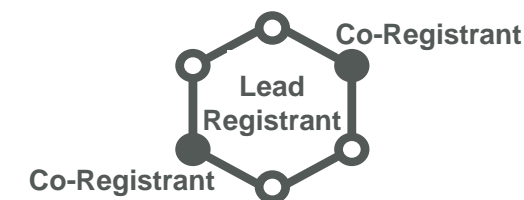


Lead-registrant:

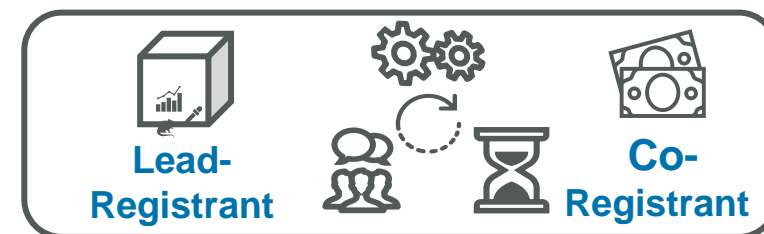
- Obligated to make a joint submission with co-registrant(s) to adhere to the “one substance, one registration” principle
- Terms & conditions of joint submission are defined in joint submission agreement
- Technically admits co-registrant (e.g. by issuing token or approving request)

Co-registrant:

- Must negotiate & sign joint submission agreement and ensure that all data (access) is completed



Joint Submission Agreement



Registration Process – Pain Points

We have identified several **pain points** that make the process particularly challenging



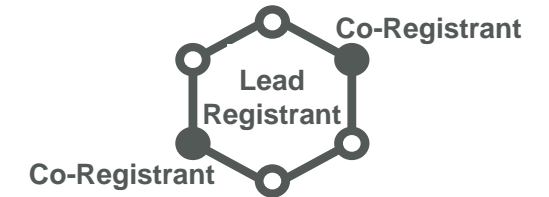
Keeping an **overview** of data, ownership and registrations



High administrative workload to **organize data access and sharing** (inquiries, invoices, payments, etc.)



High **number of cashflows** to & from various stakeholders due to reimbursement



Negotiating & **handling contracts** for data sharing and joint submission

Joint Submission – Cost Sharing with Reimbursement

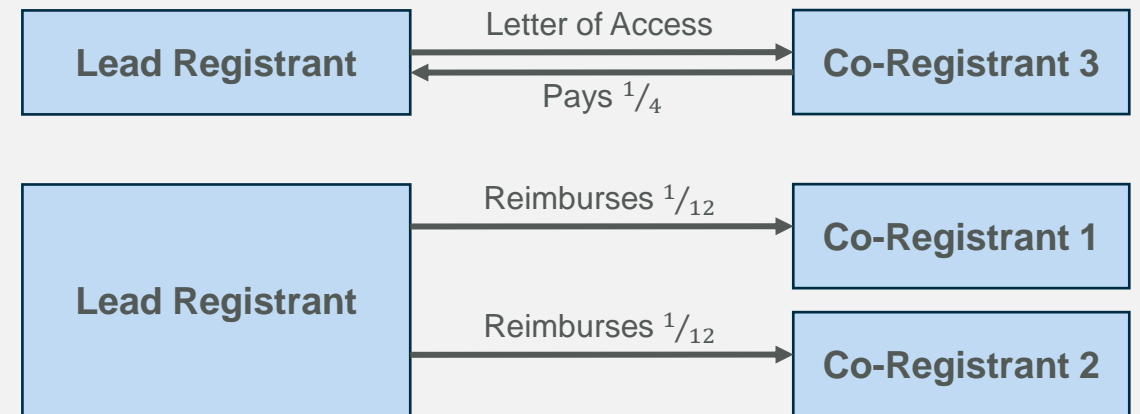
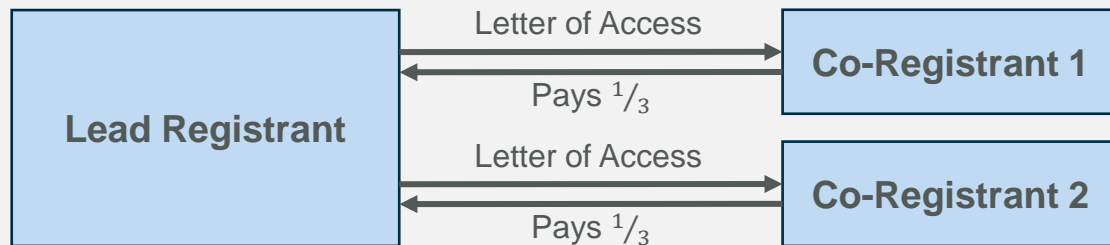
Cost Sharing Model

- Each party pays an **equal amount of costs** (i.e. for dossier preparation, CSR and study costs)
- Costs might be adjusted for tonnage band

Reimbursement

- With each new co-registrant, the costs per party will be reduced
- To keep equal cost distribution all **existing co-registrants must be reimbursed** accordingly

Example: One lead registrant & two co-registrants ... with a third co-registrant joining



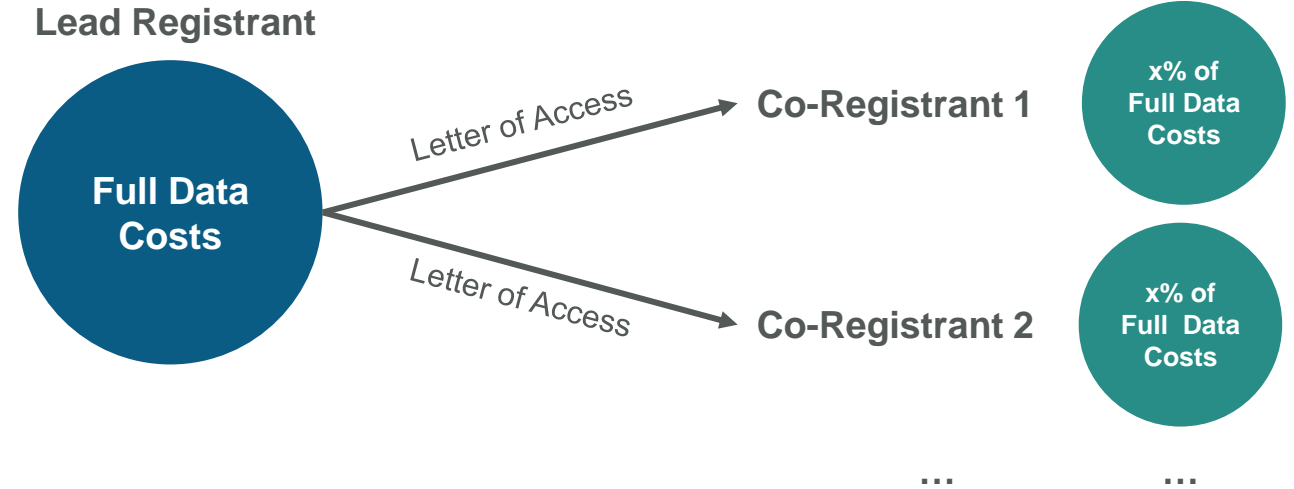
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- 1 Intro Questionnaire and Legal Background
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- 3 Simplified Data Sharing Process**
 - 3.1 Building Block #1: Simplified Data Sharing Model (non-EU)
 - 3.2 Building Block #2: Service Provider
 - 3.3 Building Block #3: Online Marketplace
- 4 Case Study - LoA Market
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Simplified Data Sharing Model - Introduction

Simplified Data Sharing Model

- Selling single licenses with usage rights instead of co-ownership
- Price is set by data owner, typically as percentage of full study costs
Examples: 3% or 5% of costs
- Each co-registrants pays the same price
- No reimbursement of existing co-registrants will be done



No reimbursement leads to significantly **reduced number of cashflows.**

Less administrative work because of less transactions

Simple & transparent pricing for all parties

Data owners have more **transparency about use of data**

Simplified Data Sharing Model - Q&A

Is the simplified data sharing model compliant with REACH-like legislations?

The simplified data sharing model is already used by several companies. In case of Lanxess, it has been reviewed and approved by relevant departments including legal, financial and regulatory. Specifically for Türkiye KKDIK, local legal advice has been consulted as well.

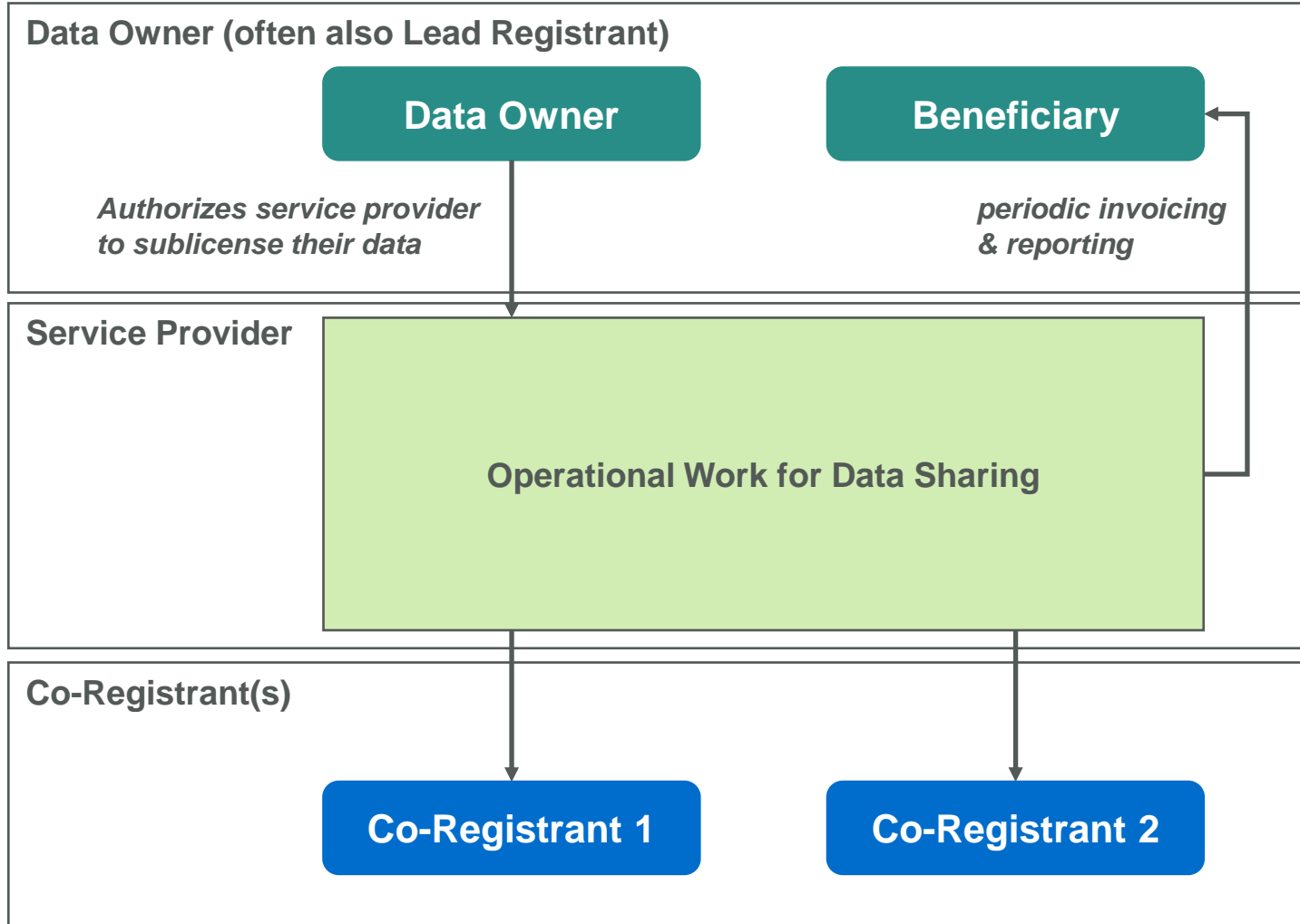
Is the price too high to remain fair? What if I start making profit?

Each company can decide how to set the price per data item. A fair and transparent price should be set, not intended to generate profits. The general idea is to charge a rather low price based on a percentage of the full study costs. Based on the experiences so far, no objections have been raised by relevant stakeholders.

Is the price too low to cover my expenses for conducting the respective studies?

Depending on the number of co-registrants, revenues from data sharing might not cover the full study costs. However, the simplified data sharing model reduces administrative workload significantly – especially if no reimbursement is done. The lower revenue could therefore be well compensated by saved administrative costs to facilitate data sharing.

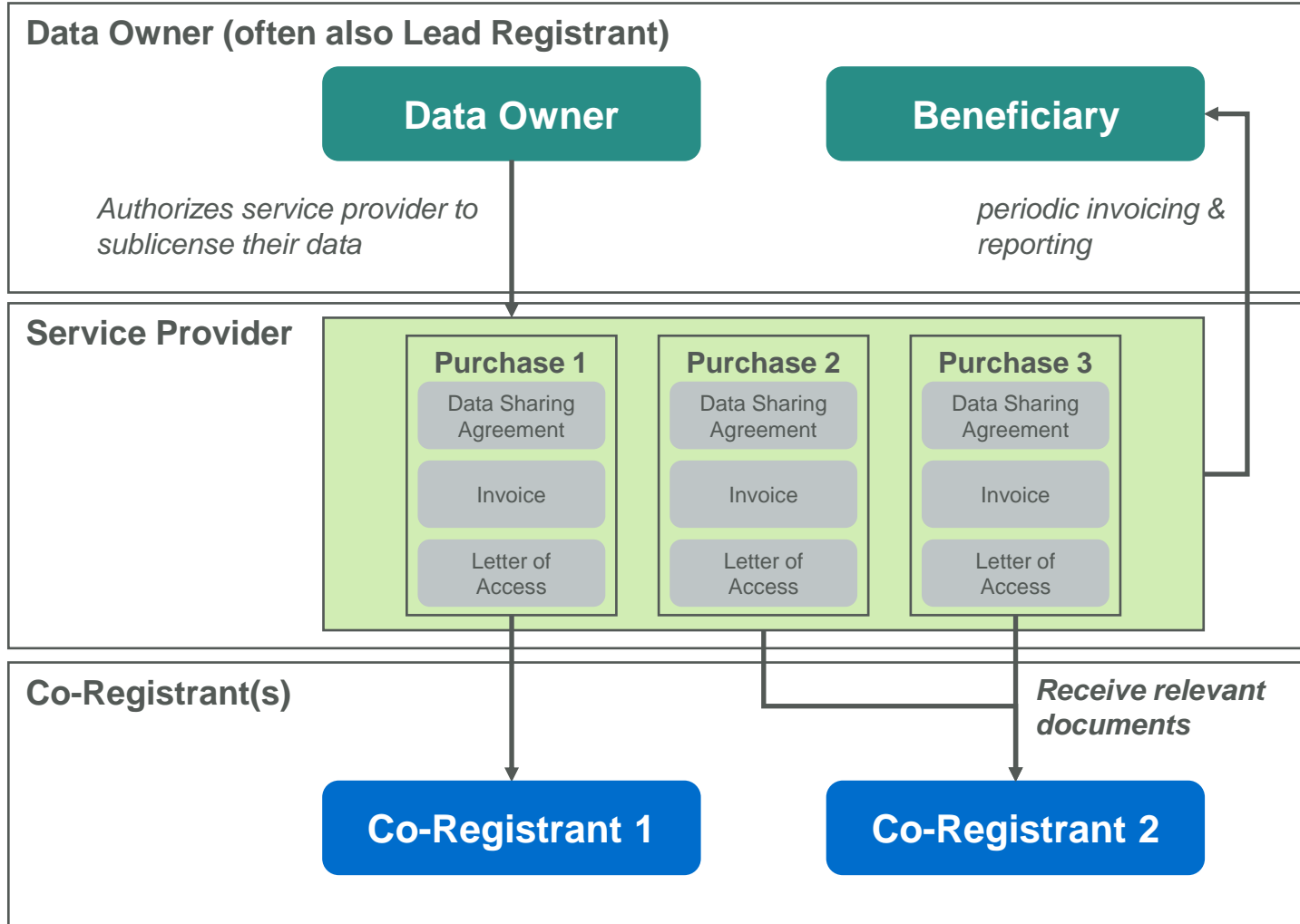
Data Sharing via Service Provider



Data Owner

- Enters data sharing agreement with service provider including right to sublicense data
 - Provides data to be shared (Studies, CSRs, IUCLID Files, Dossiers...)
 - Receive cashflows from data sharing transactions
- Data owner mainly interacts with service provider

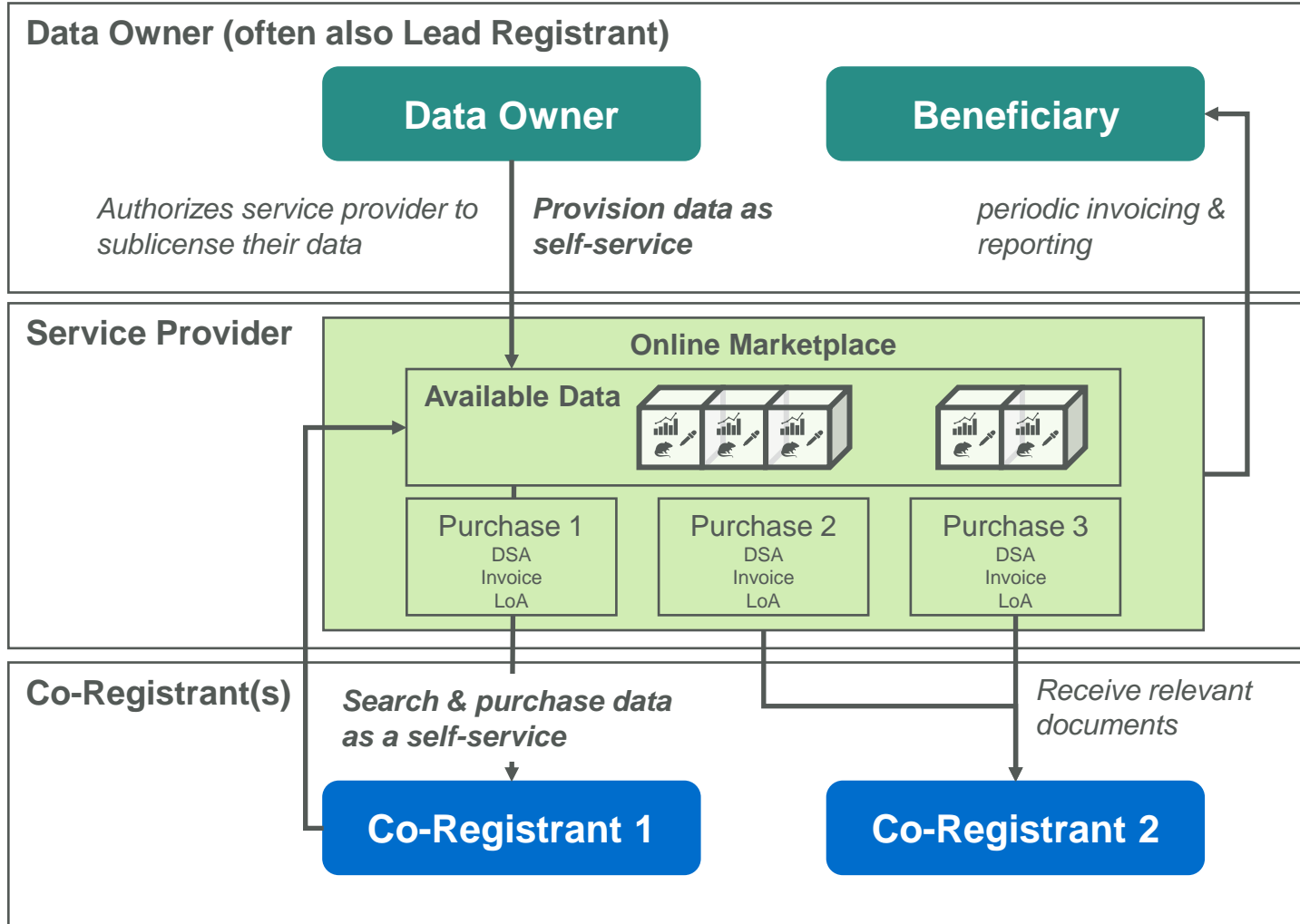
Data Sharing via Service Provider



Service Provider

- Connecting element between data owner and co-registrant(s)
- Handles administrative workload to organize data sharing (inquiries, invoices, payments)
- Enters data sharing agreements with co-registrant(s) and issues letter of access. Organizes reimbursement.
- Periodically forwards (bundled) revenues and reports to beneficiary
→ Administrative work of data sharing shifted from data owner to service provider

Data Sharing via Online Marketplace

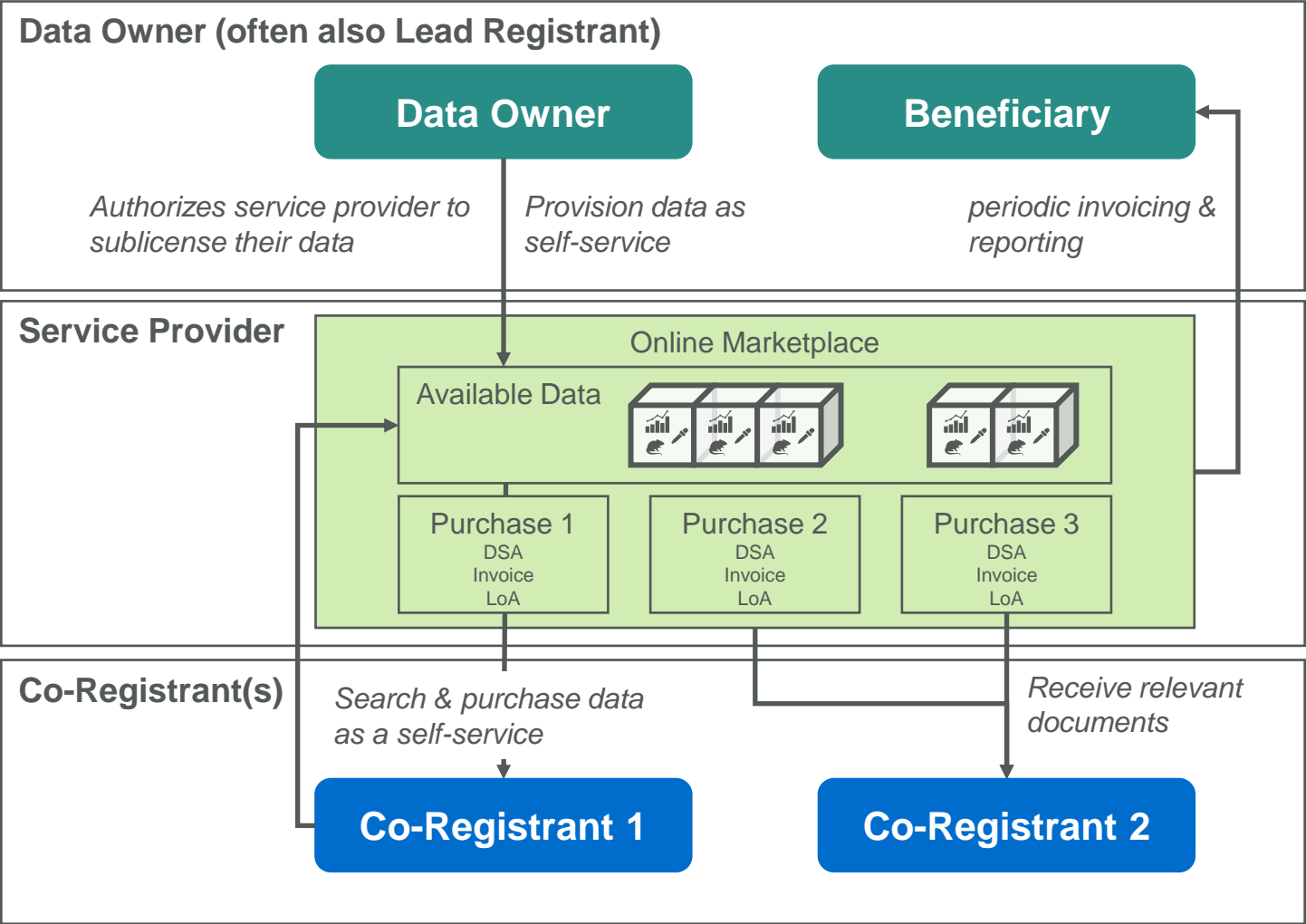


Online Marketplace

- Platform that brings together data owners and co-registrants
- Data owner maintains data to be shared – as a self-service
- Co-registrant searches and purchases data – as a self-service
- Operational work to complete data sharing transactions can be done by service provider

→ Leverage technology for an accelerated data sharing process

Combined Vision for Simplified & Accelerated Data Sharing



Vision

“One registration, one purchase”
for Data Access and Data Sharing



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Products

Filternavigation



Items 8

Sort By Product Name 

Substance	Product Name	CAS Number	EC Number
<input type="text" value=""/>	Benzaldehyde KKDIK Dossier 1-10t	100-52-7	202-860-4
	Benzaldehyde KKDIK Dossier 10-100t	100-52-8	202-860-4
	Benzaldehyde KKDIK Dossier 100-1000t	100-52-9	202-860-4
	Benzaldehyde KKDIK Dossier <1000t	100-52-10	202-860-4
	tris(2-ethylhexyl) phosphate KKDIK Dossier 1-10t	78-42-3	202-860-4
	tris(2-ethylhexyl) phosphate KKDIK Dossier 10-100t	78-42-3	202-860-4
	tris(2-ethylhexyl) phosphate KKDIK Dossier 100-1000t	78-42-3	202-860-4
	tris(2-ethylhexyl) phosphate KKDIK Dossier <1000t	78-42-3	202-860-4

Show 8 per page

Product Listing

- Data items for registration of one substance, one legislation and tonnage are bundled to a data package
- Product listing shows most relevant information to identify data package
- Data upload (add, edit or delete) as a self-service or file-based



Products

Filternavigation



Items 8

Sort By

Product Name ▾



Substance

Product Name

CAS Number

EC Number



tris(2-ethylhexyl) phosphate KKDIK Dossier 1-10t

78-42-3

202-860-4

✕ tris(2-ethylhexyl) phosphate

Jurisdiction >

Turkey ☐

Legislation >

KKDIK ☐

Tonnage >

1-10t ☒10-100t ☐100-1000t ☐>1000T ☐

Show 8 per page

Search & Filter

- Data packages can be filtered by their attributes via search or filter to find a relevant data packages for the aimed registration

→ Substance
→ CAS Number
→ EC Number
→ Product Name
→ Jurisdiction
→ Legislation
→ Tonnage

Customer Login

Registered Customers

If you have an account, sign in with your email address to view all content and information of our products.

Email *

Password *

Sign In

[Forgot Your Password?](#)

* Required Fields

New Customers

An account is required to view all content and information of our products.

Create new Account

Customer Login

- Potential buyer is asked to sign-in or create a new costumer account before detailed information about a data package will be shared
- Verification process to ensure that potential buyer have a legitimate interest in the offered data



tris(2-ethylhexyl) phosphate - KKDIK Dossier - 1-10t

	Type	Name	Year	Reliability	Data Owner	Price
<input checked="" type="checkbox"/>	Dossier	1-10t	2023		LANXESS Kimya	1,000.00 €
<input checked="" type="checkbox"/>	study report	4.6 Vapour pressure	2016	1	LANXESS Deutschland GmbH	100.00 €
<input checked="" type="checkbox"/>	study report	4.7 Partition coefficient	2016	1	LANXESS Deutschland GmbH	300.00 €
<input checked="" type="checkbox"/>	study report	4.8 Water solubility	2017	1	LANXESS Deutschland GmbH	150.00 €
<input checked="" type="checkbox"/>	study report	6.1.5 Toxicity to aquatic algae and cyanobacteria	1998	2	Government	600.00 €

Click for more details

Checkbox can be deselected

2,150€

exkl. Service Fee and VAT

Add to Cart

Lab Preview**Data Package Details**

- Data package contains data items that are required for registration
 - Dossier
 - Study
 - ...
 - Review Article/Handbook
 - Publications
- Data items can be deselected if right to refer already exists e.g., as co-data owner
- Data package might contain third-party data. Depending on the conditions, this data might be purchased inside or outside the web-shop

Home > Data packages > tris(2-ethylhexyl) phosphate KKDIK Dossier 1-10t > 4.7 Partition coefficient

4.7 Partition coefficient

Type	study report
Data Name	4.7 Partition coefficient
Endpoint Number	4.7
Endpoint Name	Partition coefficient
Title	Tris(2-ethylhexyl) phosphate: Determination of Partition Coefficient by the Slow-Stir Method
Year	2016
Author	Hein, A. M.
Reliability	1 - reliable without restriction
Adequacy	key study
Use right	Single license

Data Item Details

- Data Item Detail Page displays more detailed information that may be important to know before purchase



Checkout Process

1. Collecting grantee details that will be necessary to create the Letter of Access
2. Shipping details for the Letter of Access (E-Mail or Shipping via Mail)
3. Consent & Contract step where contract between service provider and costumer is created and consented
4. Review & Payment where costumer enters their billing information

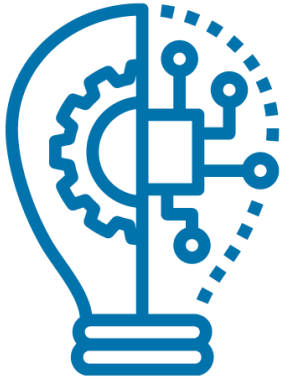
Once all steps have been completed and the payment has been received, the Letter of Access will be shipped. The Joint Submission Agreement between Lead and Co-Registrant can also be facilitated via the web-shop, i.e. by workflows to inform lead registrant and file management.

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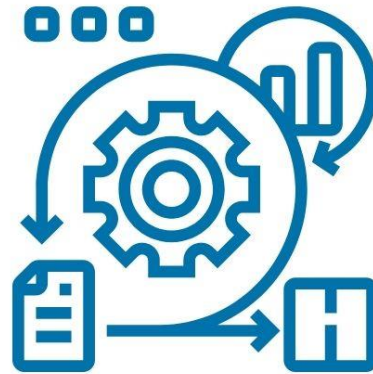
Summary

We have identified several elements that can **simplify data sharing** ...



Data Sharing Model

Simplified model that includes selling individual usage rights. Price is derived as percentage value based on study costs. No reimbursements*.



Service Provider

Data owner authorizes service provider to sell sub-licenses. All transactions will be handled by service provider. Transparent service fee, paid by buyer.



Online Marketplace

Stakeholders can interact with a web-shop as self-service. Data owners upload data. Buyers can search and purchase data.

... creating an **accelerated process** that is fair, transparent & non-discriminatory for all parties



Do you have any questions?

Get in touch with us!



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