



Quo vadis?

How to proceed with GInAS

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GInAS Project Summer Meeting2014



GInAS Today

- Application is almost ready
- Covers all substance types described in 11238 wph2
- First migration of public data starting soon
- Local installation at FDA wph1
- Some internal issues to be solved (CVs, Database)

Slide 2

wph1

This is not done yet (indicate timelines?)

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wph2

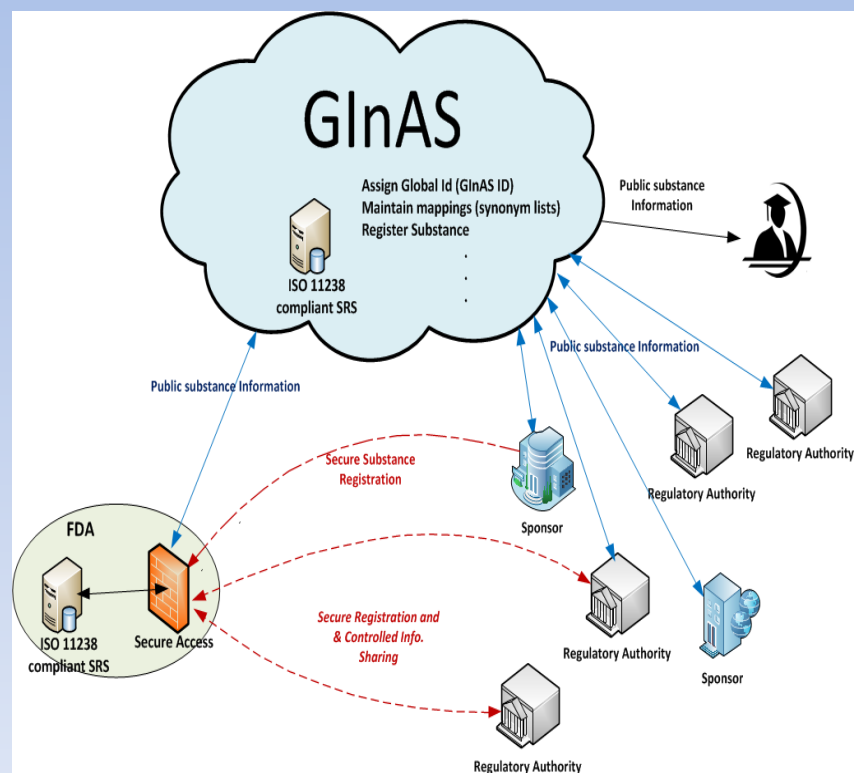
add this clarification here, to make clear which substance types are meant

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Possible GInAS Roles

- Repository of publicly available substance information and IDs
- Resource for Global Substance ID that maps to Regional IDs (Harmonization)
- Registration & Maintenance Organization for Global Unique Substance IDs wph3
- Others?



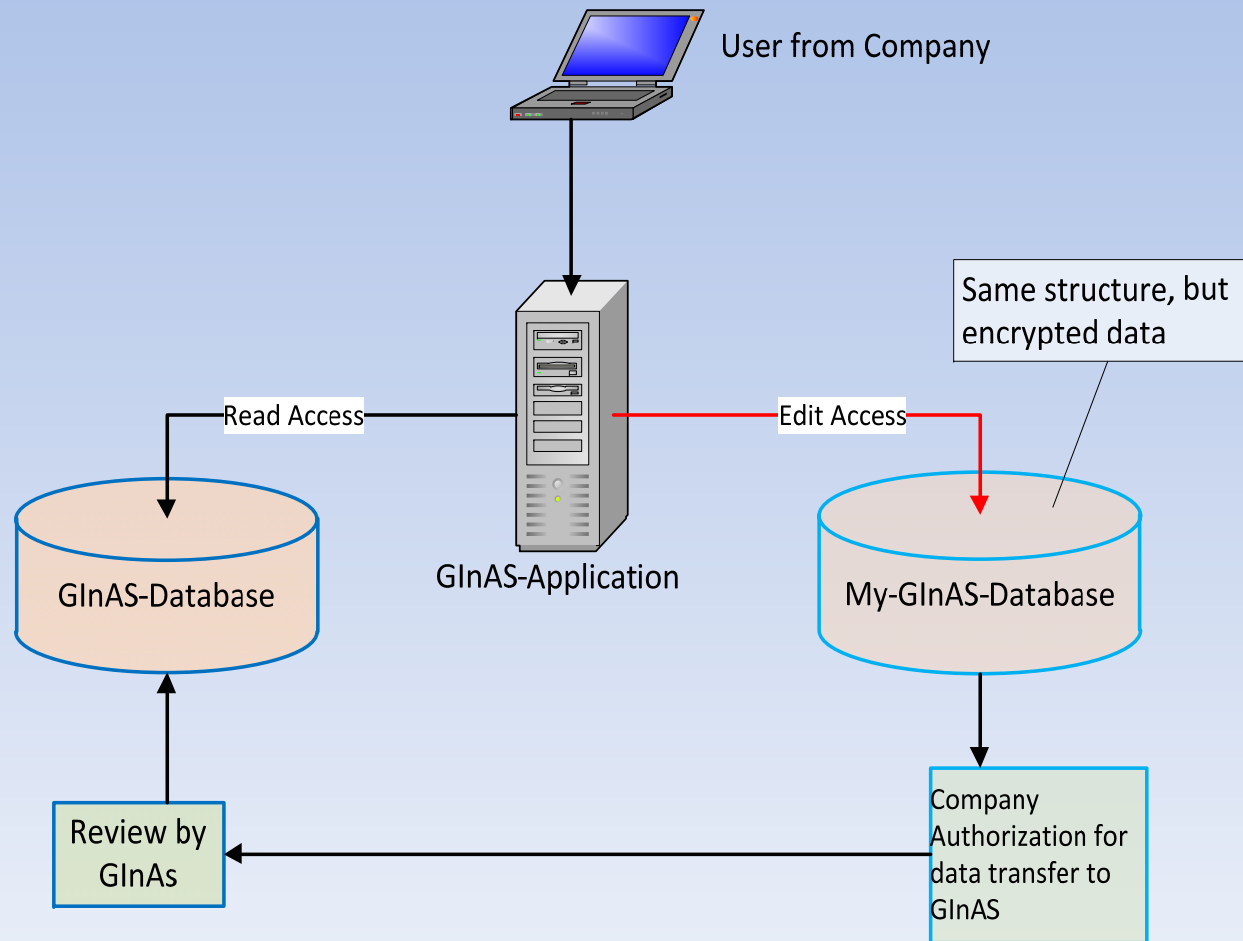
Slide 3

wph3

add "Global" here as well

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My-GInAS





Requirements for these Roles

- Repository of publicly available substance information and IDs
This requires:
 - **Availability** (24x7 ?)
 - **Accessibility** (Web, Mobile ?)
 - **Data Integrity** (Trusted source or resource only?)
 - **Repository maintenance**
 - **Funding model**
- Resource for Global Substance ID that maps to Regional IDs
All of the above requirements, plus:
 - **Authoritative (trusted) source**
 - **Governance body**
 - **Governance processes**
 - **Handling substance IDs with partial information** (FDA's confidential information issue)
- Registration & Maintenance Organization for Unique Substance IDs
All of the above requirements, plus:
 - **Additional level of governance**
 - **Ensure data confidentiality and controlled access**
 - **Service level agreement**



Company Specific Data Entry to GInAS

- Companies are allowed to enter own data to the quarantine area “My-GInAS”
- Data will be stored **encrypted** in a second instance of database
- Only the company has access to these data
- Data transfer to GInAS can be authorized by **the company only!**
- After review data will be imported into GInAS^{wph4}

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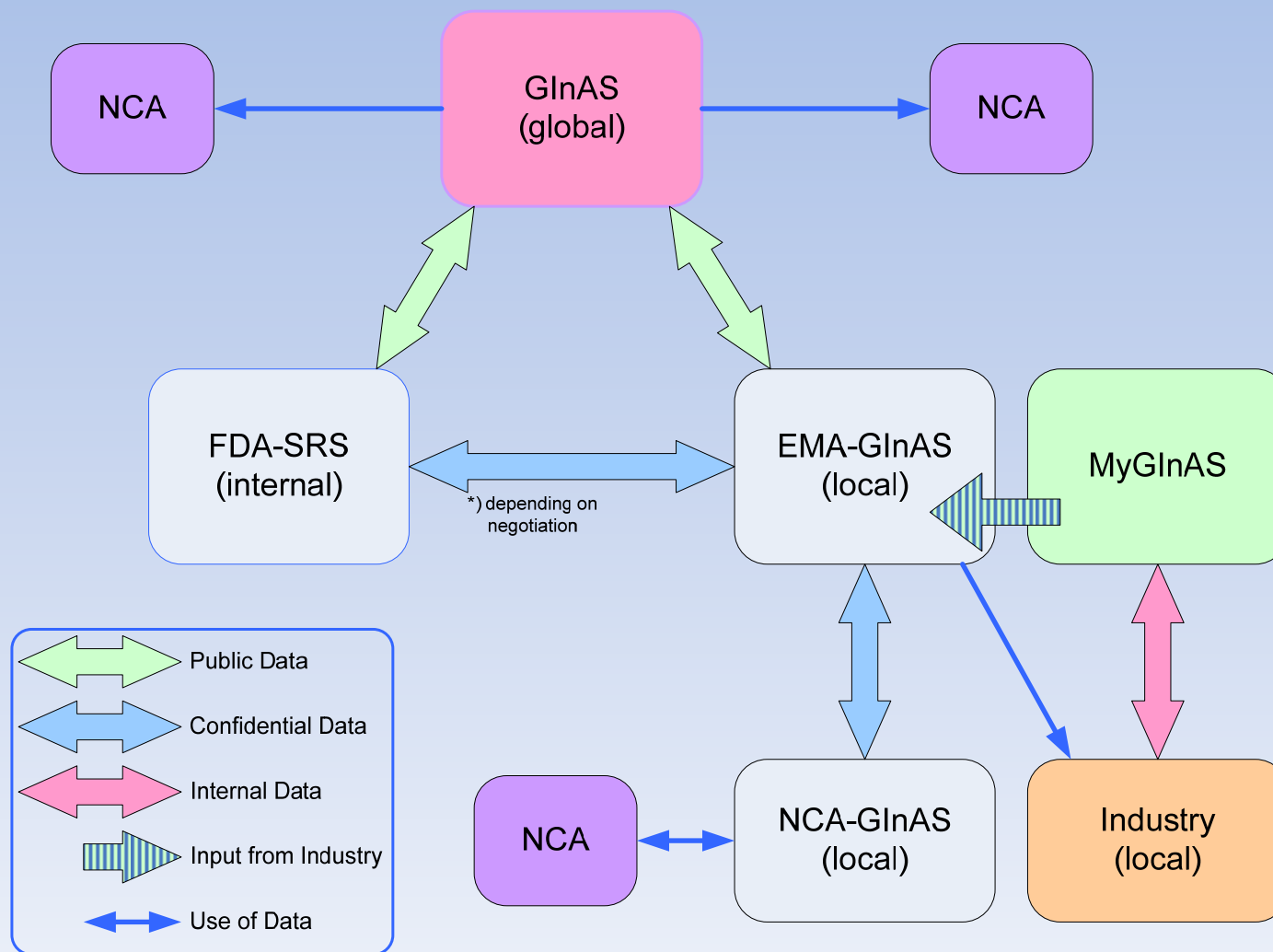
wph4

This is not clear to me

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Scenario for GInAS





How Do We Get GInAS Into Life

- Organization
 - Funding
- Governance
 - Operation
- Procedures
 - Change Management



Organization

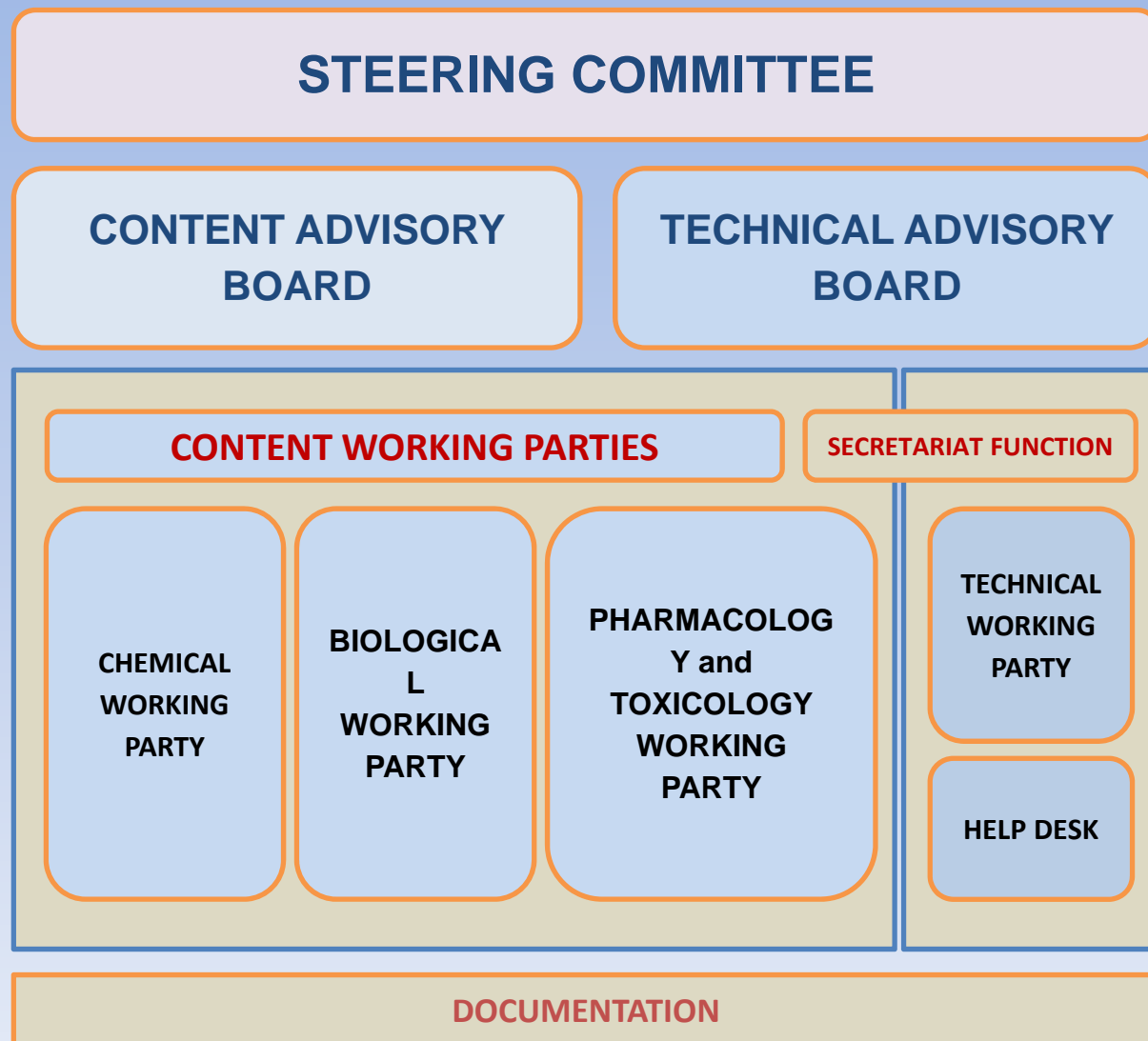
- An international reliable organisation is needed to operate GInAS
- Controlling access according to rules of GInAS
- Controlling experts work on content
- Further developement of GInAS^{wph5}
- ISO NP DTR 14872

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wph5

only an editorial change

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User Access Classification

- Guest:
 - No registration needed
 - Public domain access only!
- Organizations:
 - Roles and permissions depend on organization
 - Individual User registered/validated by organization
 - Each user is classified regarding his/her role
- **Registered users can get additional permissions**



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Change-Mangement Process

- New substances or changes undergo revision
- Receiving requests for change
- Categorization of changes
- Authorization of changes
- Producing change schedules
- Planning/building/testing changes
- Implementing changes
- Reviewing the changes for success
- Assessment for products uses results of review

Actions

- Create an international organisation that controls operation, access, changes and development of GInAS wph6
- Define rules for proper maintenance of GInAS
- Setup Groups/Boards for cooperation
- Define internal procedures to maintain contents
- **Work out synchronisation procedures**

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wph6

Editorial addition
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Thank You for your attention