Life-cycle considerations for IUCLID for PPP

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Life-cycle considerations for IUCLID for PPP

Life Cycle considerations and requirements for

- datasets

- dossier

- IUCLID generated outputs (reports)

IUCLID Datasets

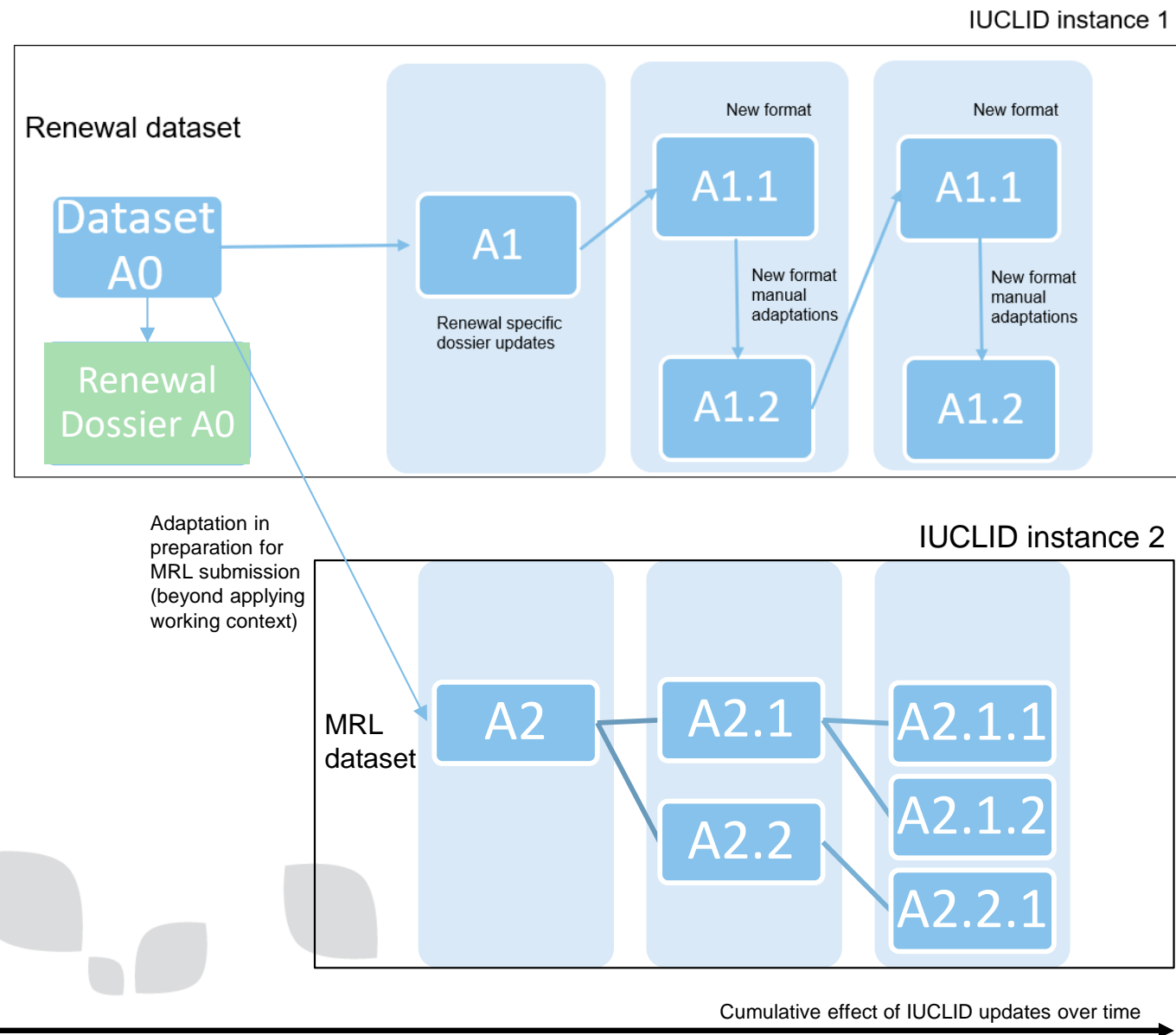- **Datasets are "live" and continually may be updated**

  - For parallel dossiers on the same active or product (i.e. Renewal + MRL) that are to be evaluated in different regulatory procedures, re-use of datasets is challenging or impossible and so creating difficulties e.g.

    - For tracking transparently what was submitted where in which version

    - Separating and maintaining parallel datasets on multiple IUCLID instances, yielding two similar datasets with common parts (to be maintained common i.e. update equally in two datasets) and differing parts (for which integrity must remain and not unintentionally updated)

- **Information may be imported/exported between IUCLID instances (*i.e.,* Applicant + Consultant) but care must be taken;**
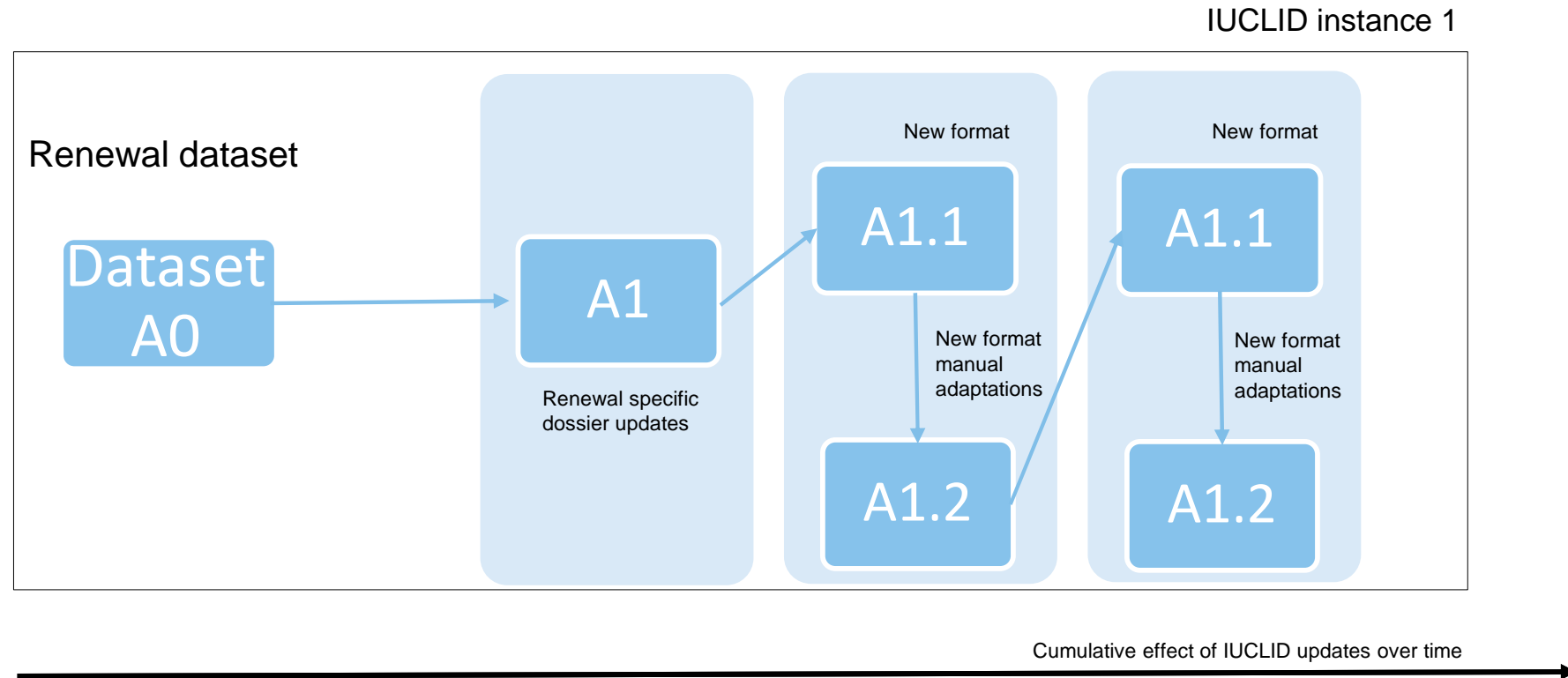
  - A dataset finalization may involve multiple parties with distributed collaboration, requiring a strict coordination of assembly
  - Multiple versions of the same information may be worked on in parallel but not combined – there is no merge function
  - Import / Export of large files is time consuming and error prone
  - Export to major previous version leads to rework of the information

- **Progression of a dataset life cycle is difficult to track due to limited audit trail and versioning.**

Illustration of profilerance of versions over lifetime of information (1/2)

Illustration of profilerance of versions over lifetime of information (2/2)

IUCLID instance 1

Renewal dataset

Dataset A0

Renewal specific dossier updates

A1

New format

A1.1

New format manual adaptations

A1.2

New format

A1.1

New format manual adaptations

A1.2

Cumulative effect of IUCLID updates over time

- Any dossier generated from the datasets reflect those „unintended" changes as well as specific update requests.

- Any item produced from a resulting dossier i.e. reports may reflect the overall change.

- Profilieration of IUCLID instances increases the overhead to maintain consistency of shared idential entities across these.

Different aspects affect the state of an originally submitted dossier

- **Dossiers are read only with a unique UUID.**

- **Once submitted in a specific format, subsequent format changes affect the included content and presentation of content, effectively creating a new version of dossier – still with the same UUID**

  – Any reference to that UUID between parties relies on using the exact IUCLID version to view it.

- **If those changes specifically require update by an applicant, this also results in a subsequent version.**

  – These changes may be direct impact i.e. the need to reinsert information, or indirect i.e. to react to a new validation rule as to enable submission of the update.
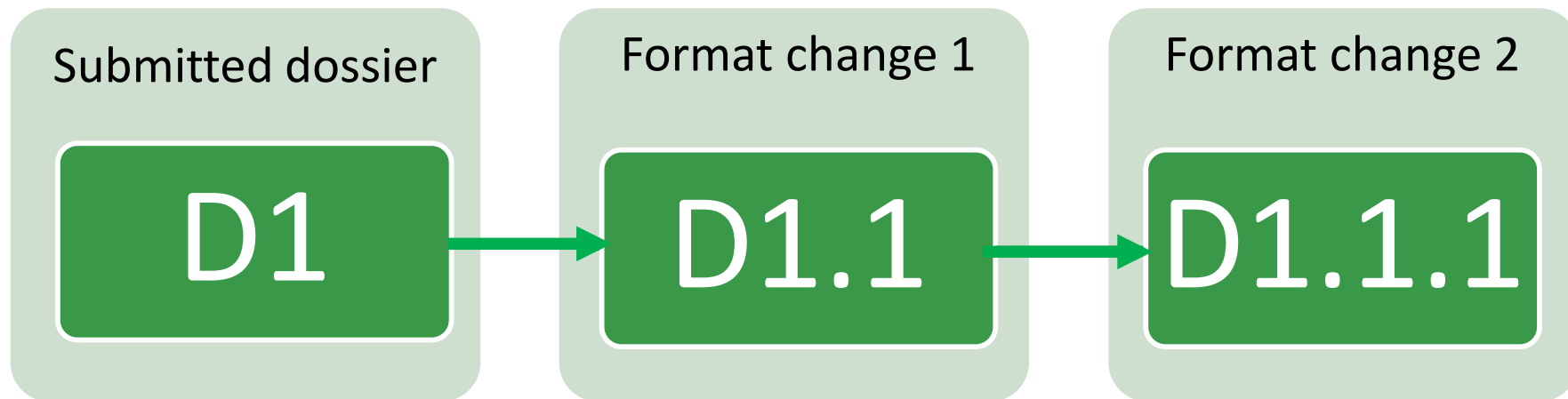
Significant rework of a dossier would be required when IUCLID version changes; risk of loss of information submitted

Current	
Subject	
Free text: we used study X with parameters Y and Z at location B and result is C.	

New version	
Subject	**Value**
Study	
Parameter 1	
Parameter 2	
location	
results	

- **Data format changes require migration rules on existing data**

- **Significant impact on affected free text fields**

  – Instead, this information is moved and stored at the end of a dossier in raw text.

Impact on life cycle of dossiers by IUCLID updates

Submitted dossier	Format change 1	Format change 2
D1	**D1.1**	**D1.1.1**

- **Changes to a submitted dossier by IUCLID update affects what is published on OpenEFSA**

- **Any output based on dossiers experiencing data format or due to changes in ruleset (report, validation, dissemination) is affected accordingly.**

CLE Considerations on need for life-cycle concept in IUCLID

- **Significant technical/administrative rather than scientific additional steps are required**
  - Maintenance of multiple datasets
  - Integrity of dossier information for a certain dossier life cycle stage
  - Transparency of dossier progression (e.g. for a single UUID)

- **Ongoing change with inherent impact, but missing explicit links of source material (e.g. Zenodo filter rules) to those that are applied in a given IUCLID version**

- **Life cycle management, versioning, migration from old to new IUCLID versions without loss of data**

- **IUCLID life-cycle management is needed for PPP**
  - Whether in general for IUCLID or specifically for PPP as to meet the PPP framework principles
  - CropLife Europe is ready to engage and support any development