

LEO Pharma – Future Perspective on Open Source

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Statistical Programming 1

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Dermatology
beyond the skin



Agenda

- LEO's Statistical Programming Landscape, and What happens on the side
- What our neighbors do (Bioinformatics, Data & Analytics)
- Reflections
- Wishes for the future

LEO's Statistical Programming Landscape

And what happens on the side

Statistical Computing Environment:

- SAS Life Science Analytics Framework / LSAF (5.3)
- 70+ users
- Used for:
 - Clinical Reporting
 - Publications + Ad hoc analyses



R + Python + ... "on the side"



LEO's Statistical Programming Landscape

And **what happens on the side**



Statistical Programmers:

- A few utilities – Check out the posters 😊

Biostatisticians:

- Power calculations
- Niche tasks / exploratory
- Logistic Regression

LEO's Statistical Programming Landscape

And **what happens on the side**



"Preferred Process":

- Install Rstudio (locally)
- Download R-packages from e.g. CRAN or Bioconductor
- Reference data in LSAF using SDD-DC

Running R in our SCE is possible, but:

- The text editor is very "notepad"ish
- No Data Frame Viewer and no Plot Viewer
- Installation of packages is somewhat cumbersome – and costly
- Not possible to have the same package running in different versions



LEO's Statistical Programming Landscape

And what happens on the side

- Quite "traditional"



- Open Source not an interest

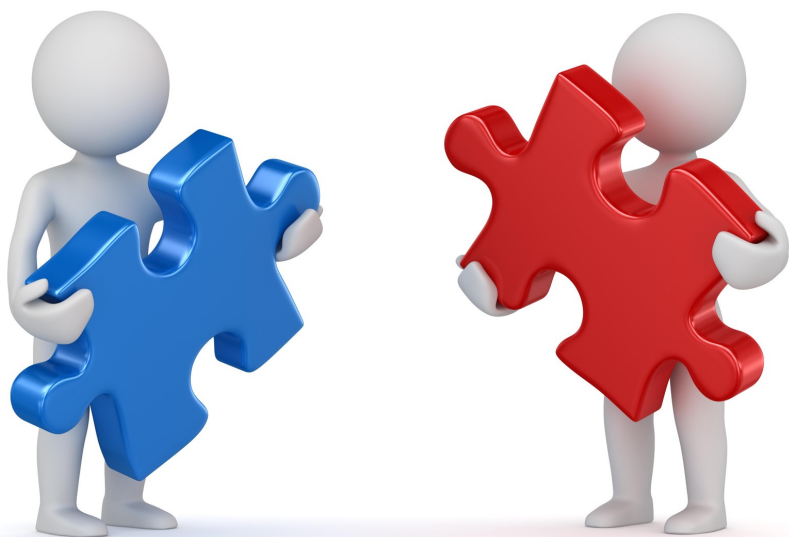
programming life



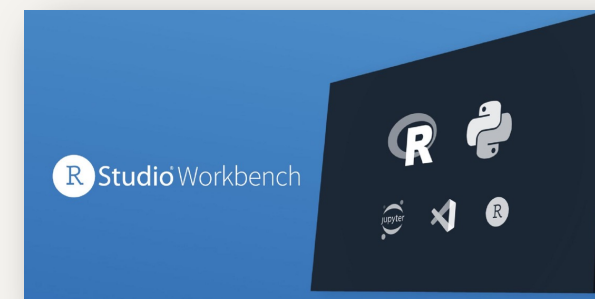
Open source
currently used case-by-case / task-based

What our neighbors do

Open Source elsewhere in LEO –
Bioinformatics

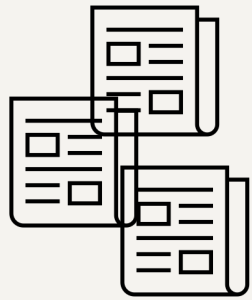


- 99% Open Source (primarily consumers)
- Perform e.g. RNA sequencing
- Disease understanding / patient characterization
- Landscape:

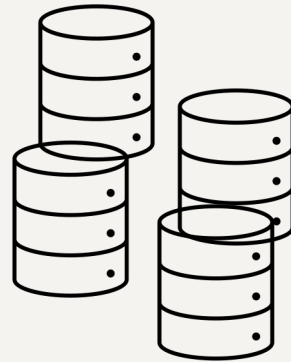


What our neighbors do

Open Source elsewhere in LEO – **Bioinformatics**



Bioinformatics
journals



Data repositories:

- Gene Expression Omnibus
- Sequence Read Archive
- European Nucleotide Archive



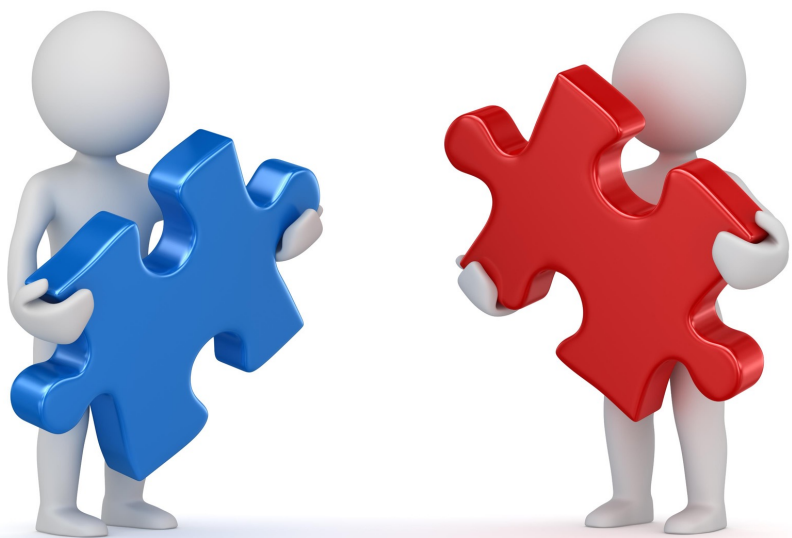
Validation:
Compare results of old
and new methods on
same data.
Look for "agreement"



New method

What our neighbors do

Open Source elsewhere in LEO –
Data & Analytics



- Using Open Source tools (and contributing)
- Software Engineering approach
- AI and Machine Learning for Drug Discovery
- Use Case:
 - AI in Drug Discovery

What our neighbors do

Open Source elsewhere in LEO – **Data & Analytics**

Use case: AI in Drug Discovery

- Building on MIT-DK cooperation
- Collaboration between Data & Analytics and MedChem I and II
- Toolset to train machine learning ("deep learning") models for drug discovery

Predict features of drug candidates using computer simulations

-> only synthesise those that have a good chance of having an effect in assay



Question



Open Source is widely used
outside the clinical setting,
but *not within*

– why?

...there seems to be so
many opportunities!

Reflections

Barriers - Technological

- Two types of barriers
 - Technological
 - Soft

Technological barriers:

- SCE – must be multilingual
- Competencies

Reflections

Barriers - soft

- "Steal with pride"
 - 1:1 vs. "Pick the community brain"
 - Fear of the Unknown (programmer?)
- Competitiveness
 - does our programming make us competitive, or is it really the molecule?
- Process Challenge / FOI – Fear of Inspections!

Reflections

Barriers - soft

- Process Challenge / FOI – Fear of Inspections!
- processes are written based on *history* – not tailored for the future
How do we handle ICH E6 in an open Source Setting:

5.5. Trial management, data handling, and record keeping

5.5.1.

The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

Wishes for the future

- Multilingual SCE
- More standardization:
 - curated code:
 - <https://pharmaverse.org/> is a great example
 - What if FDA or PMDA published curated codes on their webpages?
 - Standardization of sets (across companies)
 - Think: CDISC for formats and librefs!
- Culture
 - Processes needed to reflect the (Open Source) reality

More openness to ... Open Source 😊



Thank you

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