



Katja Glass
Consulting

Life of a Statistical Analyst

Evolving Through
Time and
Technology



Agenda



- Once Upon a Time
 - Era of Open-Source
 - Era of AI
 - Summary & Outlook
-



Once Upon a Time



Programmers
supporting the
statistician



Once Upon a Time



Datasets, tables and listings
(non-speaking names, few ascii based pages)



	Placebo (N=86)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)	Total (N=254)
Intent-To-Treat (ITT)	86 (100%)	84 (100%)	84 (100%)	254 (100%)
Safety	86 (100%)	84 (100%)	84 (100%)	254 (100%)
Efficacy	79 (92%)	81 (96%)	74 (88%)	234 (92%)
Complete Week 24	60 (70%)	28 (33%)	30 (36%)	118 (46%)
Complete Study	58 (67%)	25 (30%)	27 (32%)	110 (43%)



Once Upon a Time



SAS Programs

```
SAS: Program Editor-errors1.sas
File Edit View Tools Run Solutions Help
00001 options linesize=80;
00002 data inc;
00003   infile "income1.data";
00004   input gender race persinc;
00005   if persinc > 23 then persinc=.;
00006   var gender persinc;
00007 run;
00008
00009 title "Example 2: Read data from an external file";
00010 proc means;
00011 run;
00012
```



A little later



A little later



Analysts



A little later



- SAP
- ADAM
- TLF
- Team (DM, Statistics, Analysts, MW)
- Data checks
- Define generation
- CDISC compliance
- SOP
- Submission deliverables



Upon now



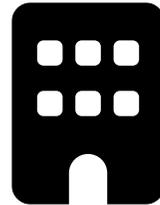
- SAP
- ADAM
- TLF
- Team (DM, Statistics, Analysts, MW)
- Data checks
- Define generation
- CDISC compliance
- SOP
- Submission deliverables
- Dashboards
- Narratives
- Intext-Tables
- Data-Insights
- AE Results Posting
- CAR Analysis
- Safety Update Reports
- De-identification



Upon now



Teaming
Standardization



Internal



Upon now



- Company adopted industry standards (SDTM, ADAM)
 - Standard programs (SAS)
 - Standard macros (SAS)
-
- Statistical Computing Environments
 - Document Systems
 - Metadata Repositories
 - Data Lakes



Agenda



- Once Upon a Time
 - **Era of Open-Source**
 - Era of AI
 - Summary & Outlook
-



Era of Open-Source



Starting Point:

- Company adopted industry standards (SDTM, ADAM)
- Standard programs (SAS)
- Standard macros (SAS)



Initial Drivers:

- Utilization of R
 - Knowledge (R programmers)
 - Broad availability of packages
 - Broad “standards” (ggplot2, Tidyverse, Shiny)
 - No license cost



Era of Open-Source



Is the effort worth switching?

Era of Open-Source



Is the effort worth switching?



Current SAS Processes

Efficiency

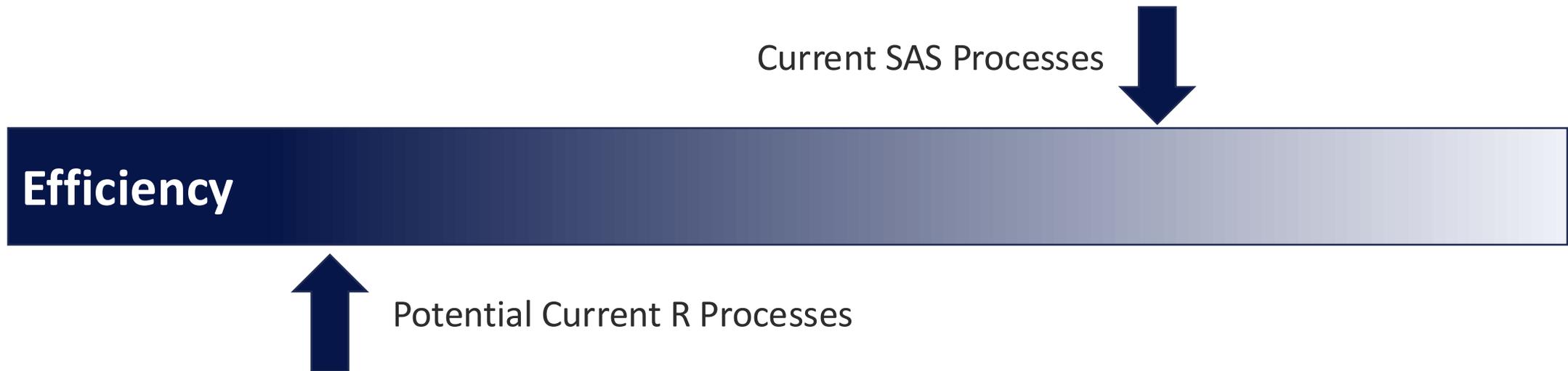
Potential Current R Processes



Era of Open-Source



Is the effort worth switching?



Era of Open-Source



Is the effort worth switching?

Current SAS Processes



Efficiency

Potential Current R Processes



Era of Open-Source



Is the effort worth switching?

Efficiency

Costs

Knowledge



Era of Open-Source



Is the effort to switch worth?

Development **Speed**



Era of Open-Source



Breaking the ice – commitments & development



Era of Open-Source



Breaking the ice – commitments & development

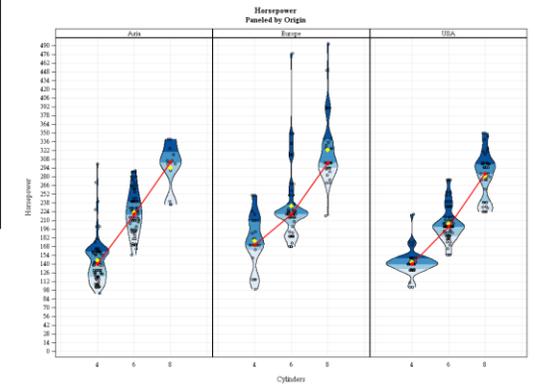
Smart Submission Dataset Viewer – XML4Pharma

DM	RELREC	CO	AE	CM	DS	EX	LB	MH	QS	SC	SE	SV	TA	TE	TI	TS	TV	VS			
STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTCT	RFENDTCT	RFXSTDTCT	RFXENDTCT	RFICDTCT	RFPENDTCT												
CDISCIPL...	DM	01-701-1015	1015	2014-01-02	2014-07-02	2014-01-02	2014-07-02		2014-07-01												
CDISCIPL...	DM	01-701-1023	1023	2012-08-05	2012-09-0a	2012-08-02	2012-09-01		2013-02-11												
CDISCIPL...	DM	01-701-1028	1028	2013-07-19	2014-01-14	2013-07-19	2014-01-14		2014-01-11												
CDISCIPL...	DM	01-701-1033	1033	2014-03-18	2014-04-14	2014-03-18	2014-03-31		2014-09-11												
CDISCIPL...	DM	01-701-1034	1034	2014-07-01	2014-12-30	2014-07-01	2014-12-30		2014-12-31												
CDISCIPL...	DM	01-701-1047	1047	2013-02-12	2013-03-32	2013-02-12	2013-03-09		2013-07-21												
CDISCIPL...	DM	01-701-1057	1057						2013-12-21												
CDISCIPL...	DM	01-701-1097	1097	2014-01-01	2014-07-09	2014-01-01	2014-07-09		2014-07-01												
CDISCIPL...	DM	01-701-1111	1111	2012-09-07	2012-09-17	2012-09-07	2012-09-16		2013-02-21												
CDISCIPL...	DM	01-701-1115	1115	2012-11-30	2013-01-23	2012-11-30	2013-01-23		2013-05-21												
CDISCIPL...	DM	01-701-1118	1118	2014-03-12	2014-09-09	2014-03-12	2014-09-09		2014-09-01												
CDISCIPL...	DM	01-701-1130	1130	2014-02-15	2014-08-16	2014-02-15	2014-08-16		2014-08-11												
CDISCIPL...	DM	01-701-1133	1133	2012-10-28	2013-04-29	2012-10-28	2013-04-28		2013-04-21												
CDISCIPL...	DM	01-701-1145	1145						2013-09-11												
CDISCIPL...	DM	01-701-1146	1146	2013-05-20	2013-06-30	2013-05-20	2013-06-26		2013-07-11												
CDISCIPL...	DM	01-701-1148	1148	2013-08-23	2014-02-20	2013-08-23	2014-02-20		2014-02-21												
CDISCIPL...	DM	01-701-1149	1149	ERROR: Duplicate USUBJID in DM dataset (USUBJID)-23					2014-03-16												
CDISCIPL...	DM	01-701-1162	1162						2013-04-11												
CDISCIPL...	DM	01-701-1176	1176						2012-09-31												
CDISCIPL...	DM	01-701-1180	1180	2013-02-12	2013-03-23	2013-02-12	2013-03-18		2013-04-01												
CDISCIPL...	DM	01-701-1181	1181	2013-12-05	2013-12-12	2013-12-05	2013-12-09		2014-05-21												
CDISCIPL...	DM	01-701-1188	1188	2013-02-15	2013-03-25	2013-02-15	2013-03-24		2013-08-01												
CDISCIPL...	DM	01-701-1192	1192	2012-07-22	2013-01-20	2012-07-22	2013-01-20		2013-01-21												
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CDISCIPL...	DM	01-701-1234	1234	2013-03-30	2013-09-22	2013-03-30	2013-09-22		2013-09-21												
CDISCIPL...	DM	01-701-1239	1239	2014-01-11	2014-07-11	2014-01-11	2014-07-10		2014-07-11												
CDISCIPL...	DM	01-701-1240	1240						2013-09-21												

SAS Unit – HMS Analytical Software

The screenshot displays the SAS Unit interface. On the left, a tree view shows the project structure. The main window is titled 'SASUnit quick results' and shows a 'Test scenario' with a table of test cases. The table has columns for Scenario ID, Exam, Description, Result, Exam ID, and Start. The results are mostly 'Pass'.

Scenario ID	Exam	Description	Result	Exam ID	Start
000	001	test_scenario	Pass	204	20090216 10:21:03
000	002	test_scenario	Pass	204	20090216 10:21:26
000	003	test_scenario	Pass	204	20090216 10:21:57
000	004	test_scenario	Pass	204	20090216 10:21:51
000	005	test_scenario	Pass	204	20090216 10:21:40



R & Shiny tools from RhoInc

Era of Open-Source



R Processes and Tools

- Roche, GSK, Novo Nordisk, J&J, ...
- Admiral + sub-packages
- Pharmaverse
- Teal (Shiny TLFs)
- Carver (Shiny TLFs)
- DaVinci (Shiny TLFs)



<https://pharmaverse.org/>

Era of Open-Source

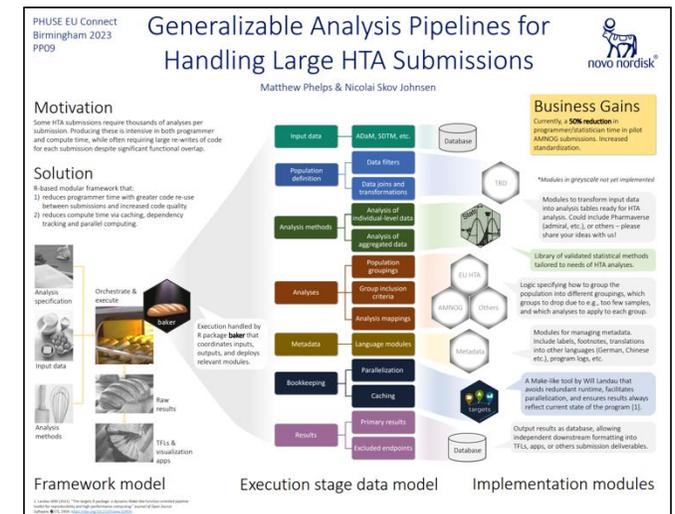


R Processes and Tools

➤ Teal4Real (Real World Data)

	Regimen A (N=118)	Regimen B (N=107)
Pharmac		
0	14 (11.8%)	49 (45.8%)
1	61 (51.3%)	52 (48.6%)
2	43 (36.1%)	6 (5.6%)
3	1 (0.8%)	0
Age		
Mean (SD)	63.3 (8.1)	61.5 (8.1)
Median	64.0	62.0
Min - Max	39.0 - 81.0	39.0 - 82.0

➤ RAMNOG (HTA-Analysis)



<https://genentech.github.io/Teal4Real/>
<https://hta-pharma.github.io/ramnog/index.html>

Era of Open-Source



Open Source Portal

<https://glacon.eu/portal>

CDISC COSA Repository

<https://cosa.cdisc.org/>

Pharmaverse

<https://pharmaverse.org/>

OpenPharma

<https://openpharma.github.io/>

446

Total repos



Era of Open-Source



Era of Open-Source



Era of Open-Source



Challenge of Choice!



Era of Open-Source



Challenge of Change!



Era of Open-Source



- Guidance
- Standardization
- Support
- User Adoption



Era of Open-Source



Opportunities



Era of Open-Source



 **UPCOMING WEBINAR**



COSA SPOTLIGHT
Informational Webinar

25 MARCH | TUESDAY
11 AM-12:30 PM ET

Topics:
Dataset-JSON Viewer
Hackthon Results & Winners
Project siera







VDE Dataset Viewer
(Dmitry Kolosov)

Open Dataset-JSON
(Junze Zhang,
Yuxin Shen)

Smart Submission
Dataset Viewer
(Jozef Aerts)

+ 4 solutions

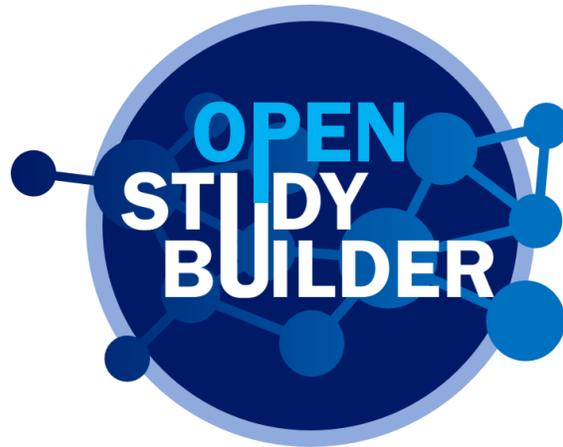
Era of Open-Source



End-2-End standardization too complex

Apart from theoretical work, need to see standards in action

360i – Moving from Proof of Concept to Implementation



ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Introducing the...

Digital Data Flow (DDF) Initiative

Era of Open-Source



- Consider where you are, where you could be
- R is developing fast and diverse
- Company focus and guidance needed
- Which initiatives to follow
- Where to participate
- Standardization
- User Adoption



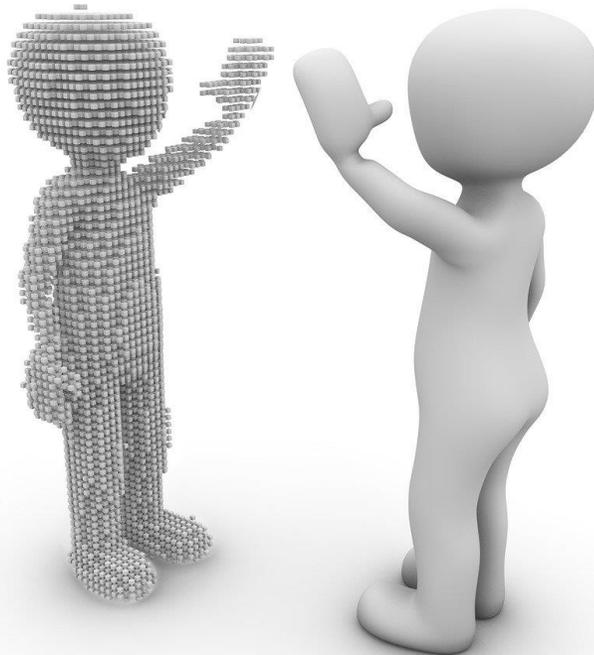
Agenda



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 - Era of Open-Source
 - **Era of AI**
 - Summary & Outlook
-



Era of AI



Era of AI



From 15 weeks to 10 minutes:
Novo Nordisk now drafts
clinical study reports -
hundreds of pages each -
with AI.

Applied AI

Ozempic Maker Says AI Is Finally Reliable Enough to Produce Sensitive Documents



Photo by Shutterstock

Era of AI



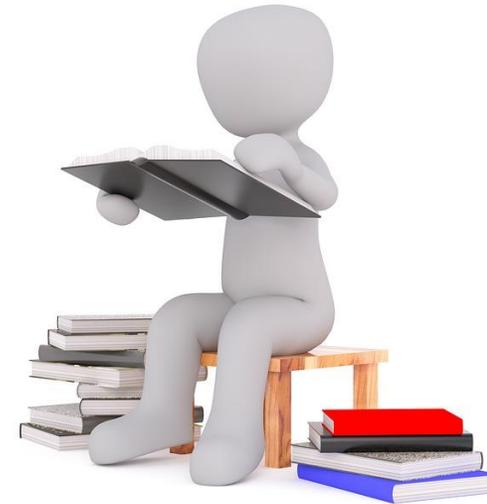
- GenAI outperformed expectations
- AI is good for tasks often performed
- How high is your study effort for
 - Standard deliverables
 - Study-specifics
- How often you need to deviate from standard?
- How often do you have exceptions?
- How often to face new requirements?



Era of AI



When you struggle on
how to do things,
how could AI know?



Era of AI



Device support

Interactive Visualizations

Continuous **change**

Chat Bot

Digital Protocol
(USDM, M11)

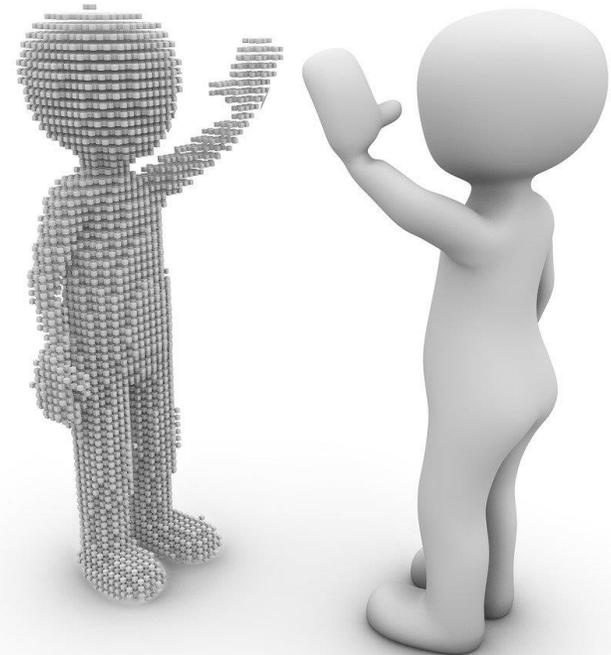
ARS & ARD

...

Era of AI



AI assistant





Information

Guidance

Standards

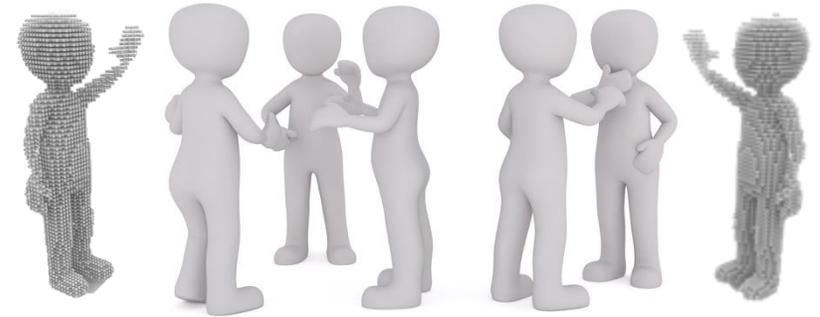
Documentation



Era of AI



- Hopes & expectations are high
- AI assistant can help us
- AI will not replace us (as available today)
- Reliability and determinisms
- Continuously new deliverables & challenges



Agenda



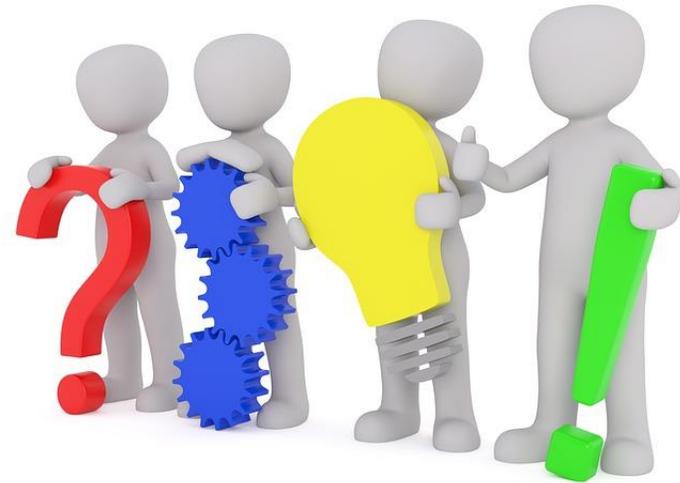
- Once Upon a Time
 - Era of Open-Source
 - Era of Agents - AI Utilization
 - **Summary & Outlook**
-



Summary and Outlook



- Disruptive changes are around
- Benefit from availability of open-source
- Benefit from opportunities of AI
- Support utilization
- Collaborate intern/extern



Summary and Outlook



➤ Less choice is easy



➤ More choices are better



Summary and Outlook



Change might be **frustrating**

Summary and Outlook



Communication is key



Summary and Outlook



Too much choices
to handle **along**



Summary and Outlook



Walk that road **together!**

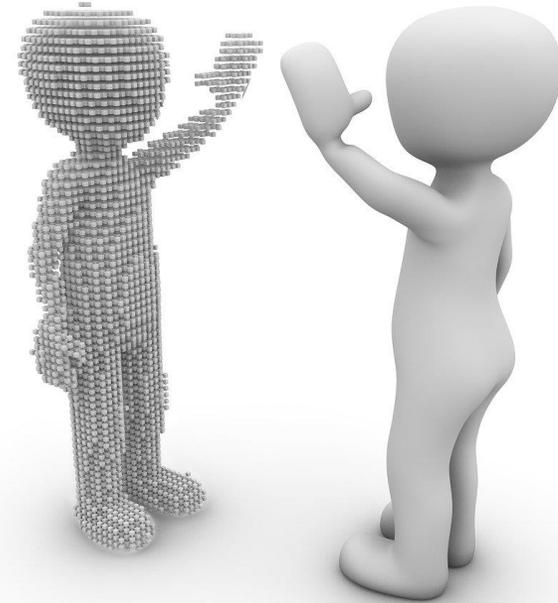
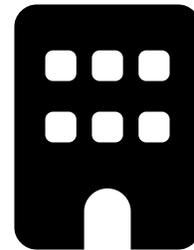
Summary and Outlook



pharmaverse



Benefit from all **help** available!



Questions?



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www.glacon.eu/portal
