
Innovation in the exploratory/regulatory Clinical Trials analysis

SA06 - Submissions & Agencies, PHUSE EU Connect 2020

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Innovations in Clinical Trial analysis

Visions for future

Clinical Trial data analysis: regulatory v. exploratory

Industry, HA collaboration and open sourcing

Innovations in Clinical Trial analysis

- Technological innovations:
 - cloud based architecture
 - dockers and containers
 - open source technologies: R, Python, others
 - interactive visualisations in reporting
- PHUSE working group - Statistical Computing Environments is working to describe the Ideal Future State for the business process supported by Statistical Computing Environments (SCEs)¹

How those technological innovations can be leveraged in changing the paper based reporting into platform independent innovative solutions/workflows supporting regulatory and exploratory reporting activities?

¹ - https://www.phusewiki.org/wiki/index.php?title=Statistical_Computing_Environments

Innovations in Clinical Trial analysis

What are potential expectations from innovations?

- utilize new technological capabilities: infrastructure and programming languages
- increase effectiveness in the clinical trial analyses, with increasingly complex clinical studies
- lower the overall cost
- leverage potential collaborations in solving common problems
- influence changes in the industry together with the health authorities
- attract new programming talents

Innovations in Clinical Trial analysis

Visions for future

Clinical Trial data analyses: regulatory versus exploratory

Industry, HA collaboration and open sourcing

Visions for future

Cloud based architecture, provides:

- Services
- Computing power
- Storage

Applications: monitoring, content, communication, ...

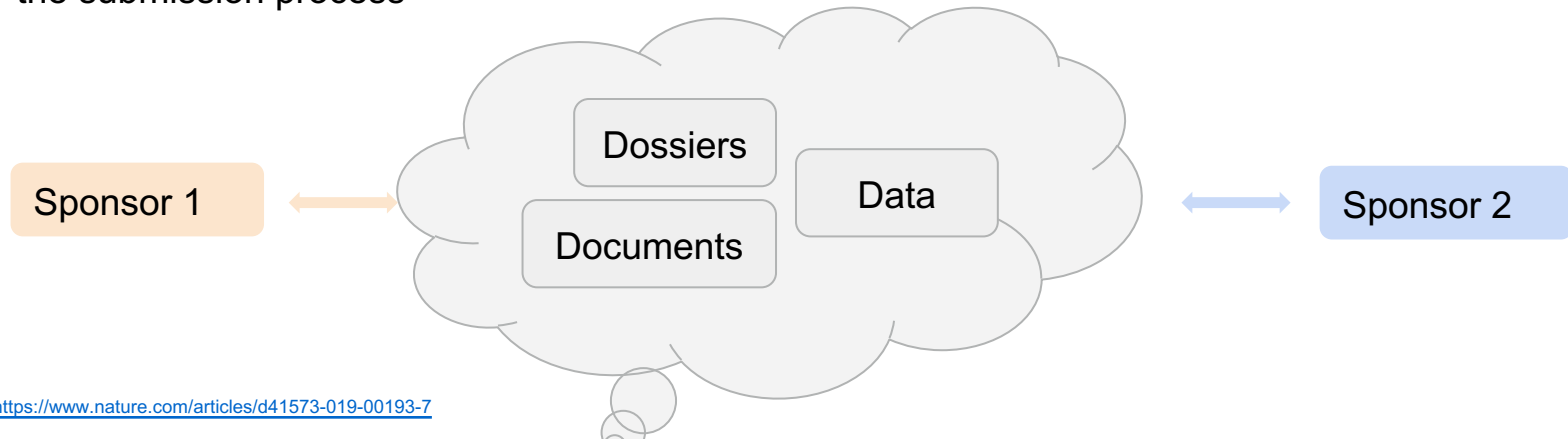
Platform: security, database, queueing, ...

Infrastructure: computing power, network, storage, ...

Visions for future

Cloud-based data systems in drug regulation: an industry perspective ²

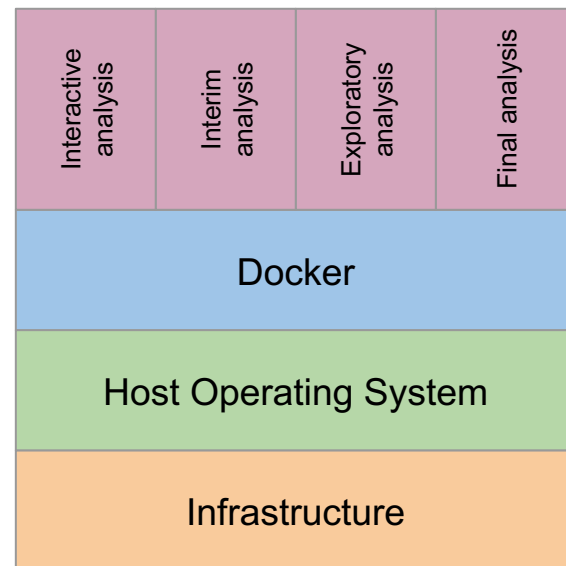
- Across companies initiative to leverage the cloud based technology to improve the regulatory submissions and transitioning to the **global, secure and accessible cloud platform**.
- It has potential to reduce the administrative burden, speed up regulatory authorities to review, conduct analysis in decision making.
- It is a transparent and more flexible solution in exchanging required documents, dossier and data in the submission process



Visions for future

Dockerized solutions

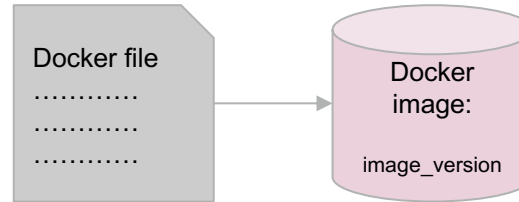
- Docker containerization provide by far the best **reproducibility** available
- Kubernetes ³ has become standard for container orchestration and allows the **platform independent** solutions
- **Scalability** - resource availability demand can scale up or down as needed
- **Shareability/transferability** - it opens a door into smooth sharing of the results with other parties: health authorities, payers without granting access to the native sponsor systems



Visions for future

What is a docker and how it really works?

- Docker image build from the dockerfile



- Docker pull the chosen docker image version

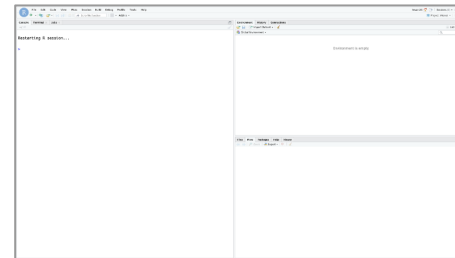
```
docker pull repository/.../image_version
```

- Create a container - a self-contained computing environment

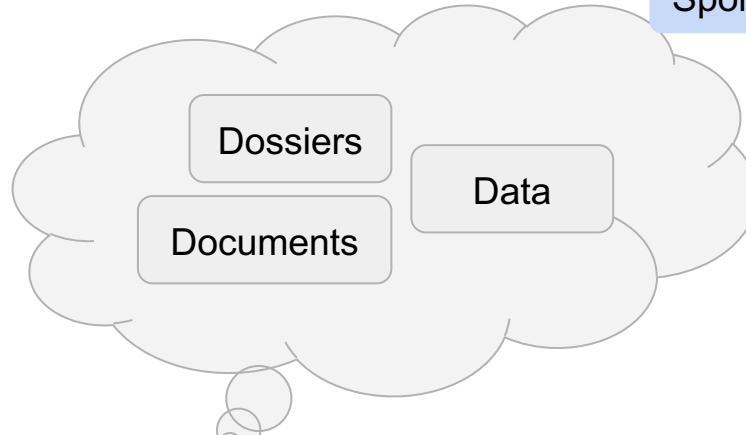
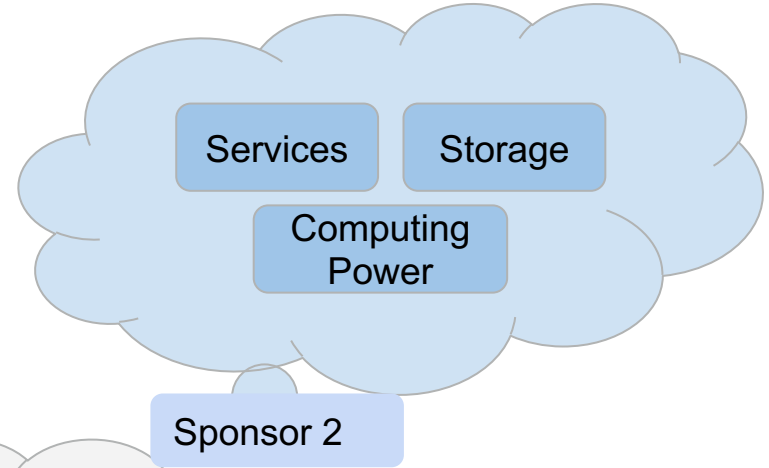
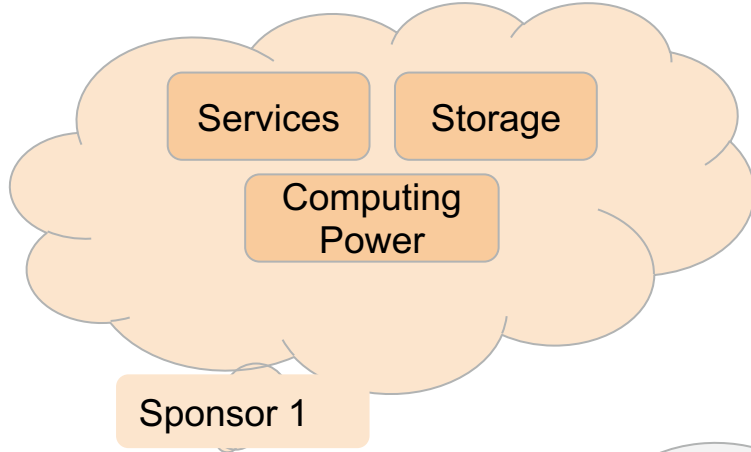
```
docker run -e PASSWORD=xxxx -p xxxx:xxx repository/.../image_version
```

- Run docker container on local host - RStudio

```
http://localhost:8787
```



Visions for future



Innovations in Clinical Trial analysis

Visions for future

Clinical Trial data analysis: regulatory v. exploratory

Industry, HA collaboration and open sourcing

Clinical Trial data analysis: regulatory v. exploratory

How to gain efficiency in clinical trial data analysis?

Example of implementation using the *R Shiny Applications within Ophthalmology* ⁴:

- Efficiency gain by combining study results exploration with analysis code generation
- Flexible and agile solutions in increasingly growing complexity of studies
- Intuitive framework as study tables, listings and graphs viewer
- Customisations of study specific implementations using the R packages
- Platform-independent solution which could change the results would be shared with HA (from PDF to interactive framework)

Clinical Trial data analysis: regulatory v. exploratory

Study Information
Data Table
Variable Browser
Demographic Table
Forest Plots
Kaplan Meier Plot
Response Table
Time To Event Table
Cross Table
Cox Reg
Logistic Reg
MMRM
Binary Response

Encodings

Analysis data: **ADSL**

Arm Variable

⌵ ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables

⌵ AGE Age, ⌵ SEX Sex, ⌵ RACE Race

⌵ Additional table settings

Show R Code

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age				
n	134	134	132	400
Mean (SD)	33.77 (6.55)	35.43 (7.9)	35.43 (7.72)	34.88 (7.44)
Median	33	35	35	34
Min - Max	21 - 50	21 - 62	20 - 69	20 - 69
Sex				
n	134	134	132	400
F	79 (58.96%)	82 (61.19%)	70 (53.03%)	231 (57.75%)
M	55 (41.04%)	52 (38.81%)	62 (46.97%)	169 (42.25%)
Race				
n	134	134	132	400
ASIAN	68 (50.75%)	67 (50%)	73 (55.3%)	208 (52%)
BLACK OR AFRICAN AMERICAN	31 (23.13%)	28 (20.9%)	32 (24.24%)	91 (22.75%)
WHITE	27 (20.15%)	26 (19.4%)	21 (15.91%)	74 (18.5%)
AMERICAN INDIAN OR ALASKA NATIVE	8 (5.97%)	11 (8.21%)	6 (4.55%)	25 (6.25%)
MULTIPLE	0	1 (0.75%)	0	1 (0.25%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.75%)	0	1 (0.25%)
OTHER	0	0	0	0
UNKNOWN	0	0	0	0

Dataset

ADSL

Obs

400/400

Subjects

400/400

Active Filter Variables

ADSL

⌵

Add Filter Variables

ADSL

Select a variable

Clinical Trial data analysis: regulatory v. exploratory

[Study Information](#)
[Data Table](#)
[Variable Browser](#)
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[Binary Response](#)

Encodings

Analysis data: ADSL

Arm Variable

ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables

T1 AGE Age, L1 SEX Sex, L2 RACE Race

Additional table settings

Show R Code

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age				
n	134	134	132	400
Mean (SD)	33.77 (6.55)	35.43 (7.9)	35.43 (7.72)	34.88 (7.44)
Median	33	35	35	34
Min - Max	21 - 50	21 - 62	20 - 69	20 - 69
Sex				
n	134	134	132	400
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UNKNOWN	0	0	0	0

Dataset

ADSL

Obs

400/400

Subjects

400/400

Active Filter Variables

ADSL

Add Filter Variables

ADSL

Select a variable

- STUDYID Study Identifier
- USUBJID Unique Subject Identifier
- SUBJID Subject Identifier for the Study
- SITEID Study Site Identifier
- T1 AGE Age
- L1 SEX Sex
- L2 RACE Race
- L3 COUNTRY Country
- INVID Investigator Identifier
- INNAM Investigator Name
- ARM Description of Planned Arm
- ARMCD Planned Arm Code
- ACTARM Description of Actual Arm
- ACTARMCD Actual Arm Code
- REGION1 Geographic Region 1
- STRATA1 Stratification Factor 1
- STRATA2 Stratification Factor 2
- BMRFK1 Continuous Level Biomarker 1
- BMRFK2 Categorical Level Biomarker 2
- ITTF Intention-To-Treat Population Flag
- SAFFL Safety Population Flag
- BMEASIFL Response Evaluable Population Flag
- BEPO1FL Biomarker Evaluable Population Flag
- EOSSTT End of Study Status
- T1 EOSDY End of Study Relative Day
- DCSREAS Reason for Discontinuation from Study
- T1 study_duration_secs NOT A STANDARD BUT NEEDED FOR RCD
- AGEGR1 Age Group

Source: agile-R website

Clinical Trial data analysis: regulatory v. exploratory

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[MMRM](#)
[Binary Response](#)

Encodings

Analysis data: ADSL

Arm Variable

ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables

T1 AGE Age, T2 SEX Sex, T3 RACE Race

Additional table settings

Show R Code

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age				
n	134	134	132	400
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NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.75%)	0	1 (0.25%)
OTHER	0	0	0	0
UNKNOWN	0	0	0	0

Dataset

ADSL

Obs

400/400

Subjects

400/400

Active Filter Variables

ADSL

AGE Age

20 25 30 35 40 45 50 55 60 65 69

☐ Keep NA (0)

STRATA1

☒ A (122)

☒ B (135)

☒ C (143)

☐ Keep NA (0)

Add Filter Variables

ADSL

Select a variable

Clinical Trial data analysis: regulatory v. exploratory

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Kaplan Meier Plot

Response Table

Time To Event Table

Cross Table

Cox Reg

Logistic Reg

MMRM

Binary Response

Encodings

Analysis data: ADSL

Arm Variable

ARM Description of Planned Arm

Add All Patients column

Summarize Variables

AGE Age, SEX Sex, RACE Race, STRATA1 Stratification Factor 1

Select All

Deselect All

AGE Age

SEX Sex

RACE Race

SUBJID Subject Identifier for the Study

SITEID Study Site Identifier

COUNTRY Country

INVID Investigator Identifier

INVTNAM Investigator Name

ARM Description of Planned Arm

ARMCD Planned Arm Code

ACTARM Description of Actual Arm

ACTARMCD Actual Arm Code

REGION1 Geographic Region 1

STRATA1 Stratification Factor 1

STRATA2 Stratification Factor 2

BMRKR1 Continuous Level Biomarker 1

BMRKR2 Categorical Level Biomarker 2

ITTFL Intent-To-Treat Population Flag

SAFFL Safety Population Flag

BMEASFL Response Evaluable Population Flag

BEPO1FL Biomarker Evaluable Population Flag

EOSSTT End of Study Status

EOSDY End of Study Relative Day

DCSREAS Reason for Discontinuation from Study

study_duration_secs NOT A STANDARD BUT NEEDED FOR RCT

AGEGR1 Age Group

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age				
n	134	134	132	400
Mean (SD)	33.77 (6.55)	35.43 (7.8)	35.43 (7.72)	34.88 (7.44)
Median	33	35	35	34
Min - Max	21 - 50	21 - 62	20 - 69	20 - 69
Sex				
n	134	134	132	400
F	79 (58.96%)	82 (61.19%)	70 (53.03%)	231 (57.75%)
M	55 (41.04%)	52 (38.81%)	62 (46.97%)	169 (42.25%)
Race				
n	134	134	132	400
ASIAN	68 (50.75%)	67 (50%)	73 (55.3%)	208 (52%)
BLACK OR AFRICAN AMERICAN	31 (23.13%)	28 (20.9%)	32 (24.24%)	91 (22.75%)
WHITE	27 (20.15%)	26 (19.4%)	21 (15.91%)	74 (18.5%)
AMERICAN INDIAN OR ALASKA NATIVE	8 (5.97%)	11 (8.21%)	6 (4.55%)	25 (6.25%)
MULTIPLE	0	1 (0.75%)	0	1 (0.25%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.75%)	0	1 (0.25%)
OTHER	0	0	0	0
UNKNOWN	0	0	0	0
Stratification Factor 1				
n	134	134	132	400
A	38 (28.36%)	44 (32.84%)	40 (30.3%)	122 (30.5%)
B	47 (35.07%)	45 (33.58%)	43 (32.58%)	135 (33.75%)
C	49 (36.57%)	45 (33.58%)	49 (37.12%)	143 (35.75%)

Dataset

Obs

Subjects

ADSL

400/400

400/400

Active Filter Variables

ADSL

AGE Age

20

25

30

35

40

45

50

55

60

65

69

Keep NA (0)

STRATA1

A (122)

B (135)

C (143)

Keep NA (0)

Add Filter Variables

ADSL

Select a variable

Clinical Trial data analysis: regulatory v. exploratory

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Time To Event Table
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Cox Reg
Logistic Reg
MMRM
Binary Response

Encodings

Analysis data: ADSL

Arm Variable

ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables

T1 AGE Age, SEX Sex, RACE Race, STRATA1 Stratification

Additional table settings

Show R Code

	A: Drug X (N=119)	B: Placebo (N=108)	C: Combination (N=109)	All Patients (N=336)
Age				
n	119	108	109	336
Mean (SD)	32.26 (5.22)	32.5 (4.96)	32.84 (4.97)	32.53 (5.05)
Median	32	32	33	32
Min - Max	21 - 41	21 - 41	20 - 41	20 - 41
Sex				
n	119	108	109	336
F	73 (61.34%)	70 (64.81%)	61 (55.96%)	204 (60.71%)
M	46 (38.66%)	38 (35.19%)	48 (44.04%)	132 (39.29%)
Race				
n	119	108	109	336
ASIAN	65 (54.62%)	52 (48.15%)	59 (54.13%)	176 (52.38%)
BLACK OR AFRICAN AMERICAN	28 (23.53%)	22 (20.37%)	25 (22.94%)	75 (22.32%)
WHITE	21 (17.65%)	22 (20.37%)	19 (17.43%)	62 (18.45%)
AMERICAN INDIAN OR ALASKA NATIVE	5 (4.2%)	11 (10.19%)	6 (5.5%)	22 (6.55%)
MULTIPLE	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.93%)	0	1 (0.3%)
OTHER	0	0	0	0
UNKNOWN	0	0	0	0
Stratification Factor 1				
n	119	108	109	336
A	35 (29.41%)	36 (33.33%)	36 (33.03%)	107 (31.85%)
B	40 (33.61%)	35 (32.41%)	32 (29.36%)	107 (31.85%)
C	44 (36.97%)	37 (34.26%)	41 (37.61%)	122 (36.31%)

Dataset

ADSL

Obs

336/400

Subjects

336/400

Active Filter Variables

ADSL

AGE Age

20 25 30 35 40 45 50 55 60 65 70

☐ Keep NA (0)

STRATA1

☒ A (122)

☒ B (135)

☒ C (143)

☐ Keep NA (0)

Add Filter Variables

ADSL

Select a variable

Clinical Trial data analysis: regulatory v. exploratory

[Study Information](#)
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[MMRM](#)
[Binary Response](#)

Encodings

Analysis data: ADSL

Arm Variable

ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables

T1 AGE Age, SEX Sex, RACE Race, STRATA1 Stratification

Additional table settings

Show R Code

	A: Drug X (N=75)	B: Placebo (N=71)	C: Combination (N=68)	All Patients (N=214)
Age				
n	75	71	68	214
Mean (SD)	31.88 (5.08)	32.25 (5.02)	32.81 (5.11)	32.3 (5.06)
Median	31	32	33	32
Min - Max	23 - 41	21 - 41	20 - 41	20 - 41
Sex				
n	75	71	68	214
F	43 (57.33%)	47 (66.2%)	37 (54.41%)	127 (59.35%)
M	32 (42.67%)	24 (33.8%)	31 (45.59%)	87 (40.65%)
Race				
n	75	71	68	214
ASIAN	40 (53.33%)	37 (52.11%)	36 (52.94%)	113 (52.8%)
BLACK OR AFRICAN AMERICAN	16 (21.33%)	14 (19.72%)	15 (22.06%)	45 (21.03%)
WHITE	15 (20%)	16 (22.54%)	13 (19.12%)	44 (20.56%)
AMERICAN INDIAN OR ALASKA NATIVE	4 (5.33%)	4 (5.63%)	4 (5.88%)	12 (5.61%)
MULTIPLE	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0
OTHER	0	0	0	0
UNKNOWN	0	0	0	0
Stratification Factor 1				
n	75	71	68	214
A	35 (46.67%)	36 (50.7%)	36 (52.94%)	107 (50%)
B	40 (53.33%)	35 (49.3%)	32 (47.06%)	107 (50%)
C	0	0	0	0

Dataset

ADSL

Obs

214/400

Subjects

214/400

Active Filter Variables

ADSL

AGE Age

20 25 30 35 40 45 50 55 60 65 70

☐ Keep NA (0)

STRATA1

☒ A (122)

☒ B (135)

☐ C (143)

☐ Keep NA (0)

Add Filter Variables

ADSL

Select a variable

Clinical Trial data analysis: regulatory v. exploratory

Study Information Data Table Variable Browser **Demographic Table** Forest Plots Kaplan Meier Plot

Encodings
Analysis data: ADSL

Arm Variable
Let ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables
T1 AGE Age, let SEX Sex, let RACE Race, let STRATA1 Stratification

Additional table settings

Show R Code

Age
n
Mean (SD)
Median
Min - Max

Sex
n
F
M

Race
n
ASIAN
BLACK OR AFRICAN AMERICAN
WHITE
AMERICAN INDIAN OR ALASKA NATIVE
MULTIPLE
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
OTHER
UNKNOWN

Stratification Factor 1
n
A
B
C

```

# Demographic Table
# ADSL
# AGE Age, let SEX Sex, let RACE Race, let STRATA1 Stratification
# Add All Patients column
# Summarize Variables
# T1 AGE Age, let SEX Sex, let RACE Race, let STRATA1 Stratification
# Additional table settings
# Show R Code
# Copy to Clipboard
# Dismiss

```

All Patients (N=214)

Age	Obs	Subjects
214	214	214
32.3 (5.06)		
32		
20 - 41		
214		
127 (59.35%)		
87 (40.65%)		
214		
113 (52.8%)		
45 (21.03%)		
44 (20.56%)		
12 (5.61%)		
0		
0		
0		
0		
214		
107 (50%)		
107 (50%)		
0		

Active Filter Variables
ADSL
AGE Age
20 35 40 45 50 55 60 65 70 75 80 85 90 95 100
Keep NA (0)

STRATA1
☒ A (122)
☒ B (135)
☐ C (143)
Keep NA (0)

Add Filter Variables
ADSL
Select a variable

Source: agile-R website

Clinical Trial data analysis: regulatory v. exploratory

Study Information Data Table Variable Browser **Demographic Table** Forest Plots Kaplan Meier Plot

Encodings
Analysis data: ADSL

Arm Variable
Let ARM Description of Planned Arm

☒ Add All Patients column

Summarize Variables
T1 AGE Age, Let SEX Sex, Let RACE Race, Let STRATA1 Stratification

Additional table settings

Show R Code

```

n
Mean (SD)
Median
Min - Max

Sex
n
F
M

Race
n
ASIAN
BLACK OR AFRICAN AMERICAN
WHITE
AMERICAN INDIAN OR ALASKA NATIVE
MULTIPLE
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
OTHER
UNKNOWN

Stratification Factor 1
n
A
B
C
  
```

Copy to Clipboard Dismiss

Dataset	Obs	Subjects
ADSL	214/400	214/400

All Patients (N=214)

214
32.3 (5.0%)
32
20 - 41
214
127 (59.35%)
87 (40.65%)
214
113 (52.8%)
45 (21.03%)
44 (20.56%)
12 (5.61%)
0
0
0
0
214
107 (50%)
107 (50%)
0

Active Filter Variables

ADSL

AGE Age

20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95

☐ Keep NA (0)

STRATA1

☒ A (122)

☒ B (135)

☐ C (143)

☐ Keep NA (0)

Add Filter Variables

ADSL

Select a variable

Clinical Trial data analysis: regulatory v. exploratory

```

72
73
74
75
76
77
78
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80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97

```

Console Terminal Jobs

```

> tbl

```

	A: Drug X (N=75)	B: Placebo (N=71)	C: Combination (N=68)	All Patients (N=214)
Age				
n	75	71	68	214
Mean (SD)	31.88 (5.08)	32.25 (5.02)	32.81 (5.11)	32.3 (5.06)
Median	31	32	33	32
Min - Max	23 - 41	21 - 41	20 - 41	20 - 41
Sex				
n	75	71	68	214
F	43 (57.33%)	47 (66.2%)	37 (54.41%)	127 (59.35%)
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WHITE	15 (20%)	16 (22.54%)	13 (19.12%)	44 (20.56%)
AMERICAN INDIAN OR ALASKA NATIVE	4 (5.33%)	4 (5.63%)	4 (5.88%)	12 (5.61%)
MULTIPLE	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0
OTHER	0	0	0	0
UNKNOWN	0	0	0	0
Stratification Factor 1				
n	75	71	68	214
A	35 (46.67%)	36 (50.7%)	36 (52.94%)	107 (50%)
B	40 (53.33%)	35 (49.3%)	32 (47.06%)	107 (50%)
C	0	0	0	0

Global Environment

Data

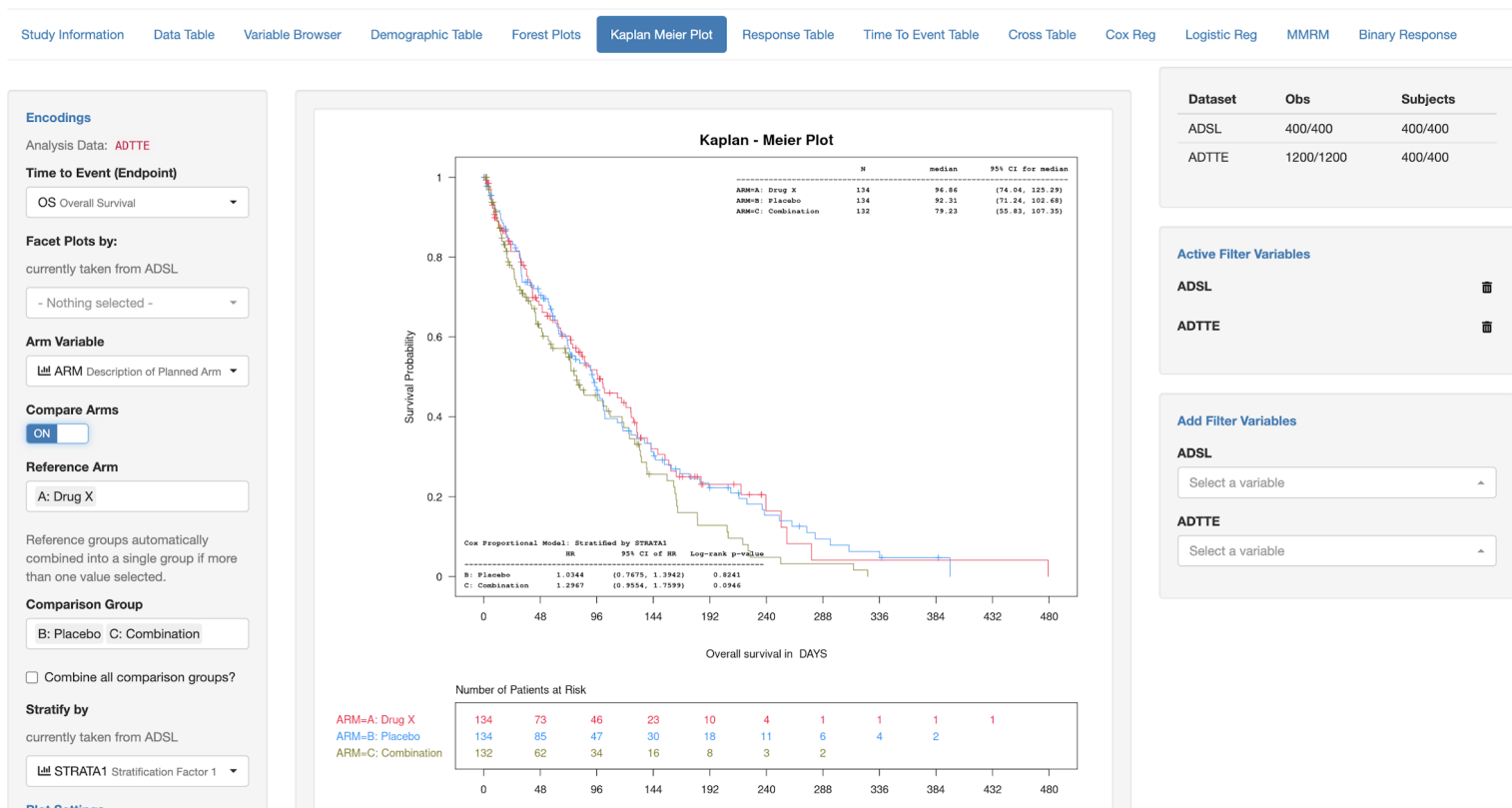
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- @ADRS 800 obs. of 43 variables
- @ADSL 400 obs. of 34 variables
- @ADSL_FILTERED 214 obs. of 34 variables
- @ADTTE 1200 obs. of 44 variables
- @ANL 214 obs. of 5 variables
- @tbl List of 27

Values

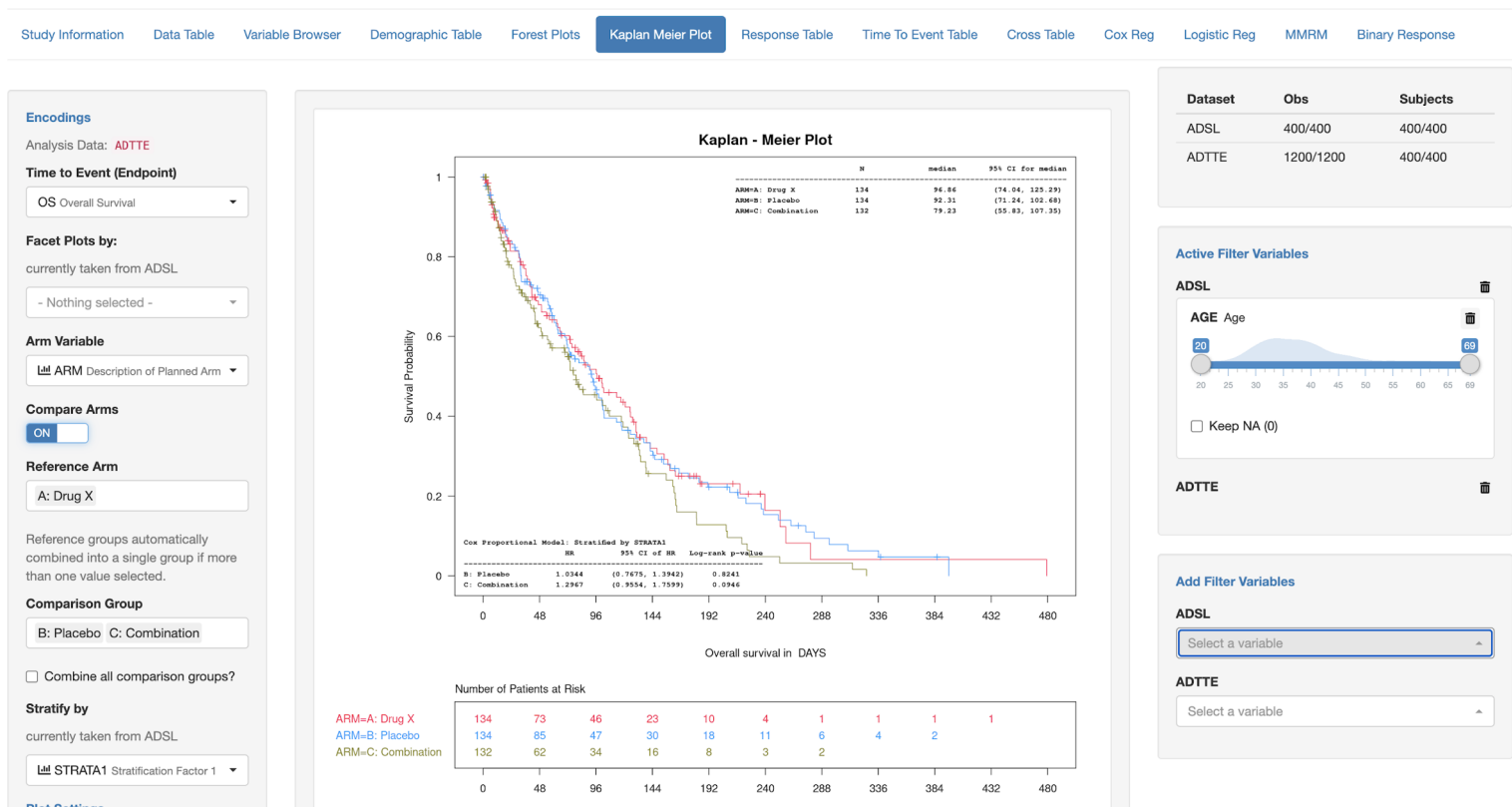
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- adsl_labels Named chr [1:34] "Study Identifier" "Unique Subject Identifier" "Subject Ide...

	A: Drug X (N=75)	B: Placebo (N=71)	C: Combination (N=68)	All Patients (N=214)
Age				
n	75	71	68	214
Mean (SD)	31.88 (5.08)	32.25 (5.02)	32.81 (5.11)	32.3 (5.06)
Median	31	32	33	32
Min - Max	23 - 41	21 - 41	20 - 41	20 - 41
Sex				
n	75	71	68	214
F	43 (57.33%)	47 (66.2%)	37 (54.41%)	127 (59.35%)
M	32 (42.67%)	24 (33.8%)	31 (45.59%)	87 (40.65%)
Race				
n	75	71	68	214
ASIAN	40 (53.33%)	37 (52.11%)	36 (52.94%)	113 (52.81%)
BLACK OR AFRICAN AMERICAN	16 (21.33%)	14 (19.72%)	15 (22.06%)	45 (21.03%)
WHITE	15 (20%)	16 (22.54%)	13 (19.12%)	44 (20.56%)
AMERICAN INDIAN OR ALASKA NATIVE	4 (5.33%)	4 (5.63%)	4 (5.88%)	12 (5.61%)
MULTIPLE	0	0	0	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0
OTHER	0	0	0	0
UNKNOWN	0	0	0	0
Stratification Factor 1				
n	75	71	68	214
A	35 (46.67%)	36 (50.7%)	36 (52.94%)	107 (50%)
B	40 (53.33%)	35 (49.3%)	32 (47.06%)	107 (50%)
C	0	0	0	0

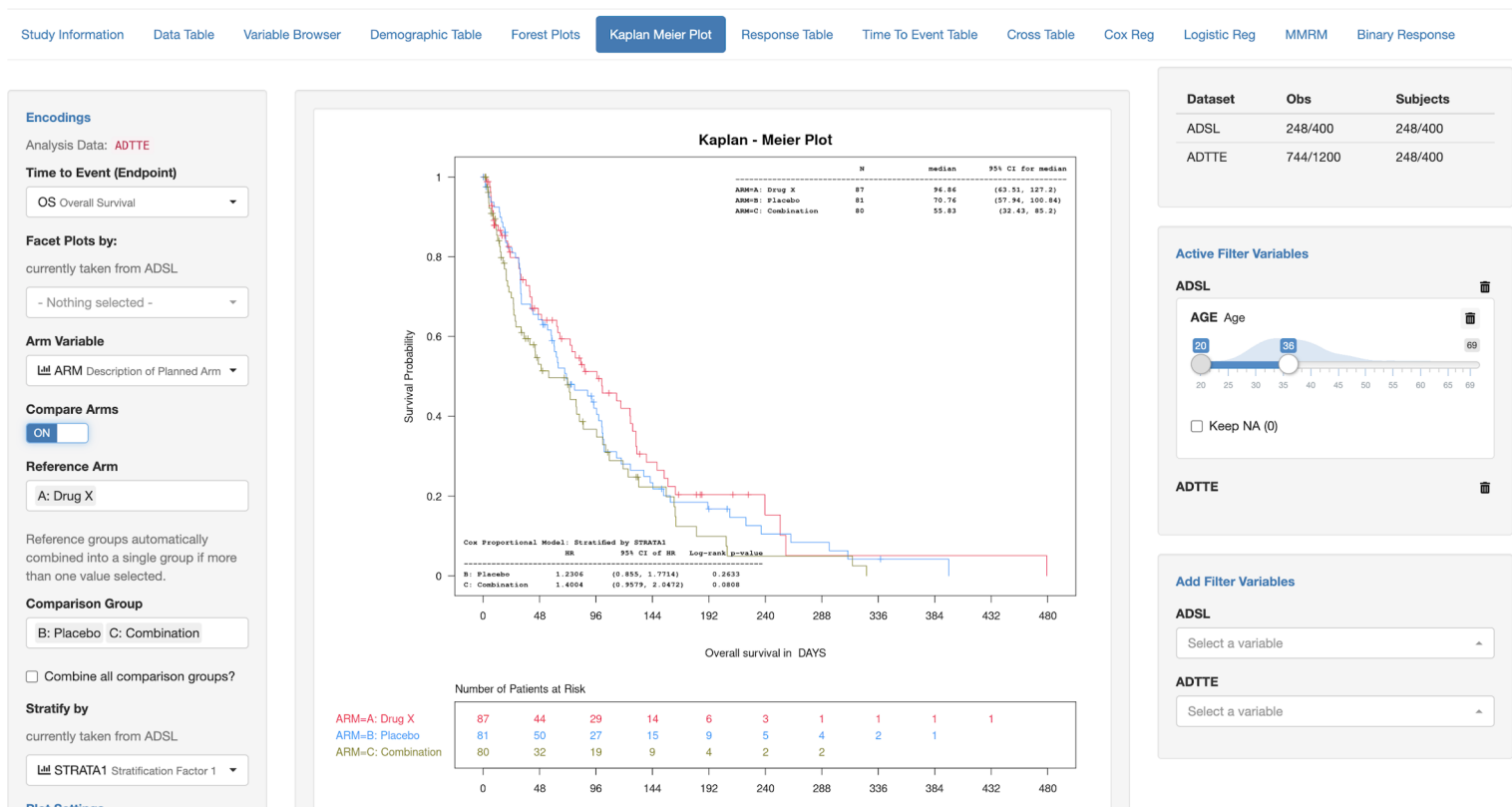
Clinical Trial data analysis: regulatory v. exploratory

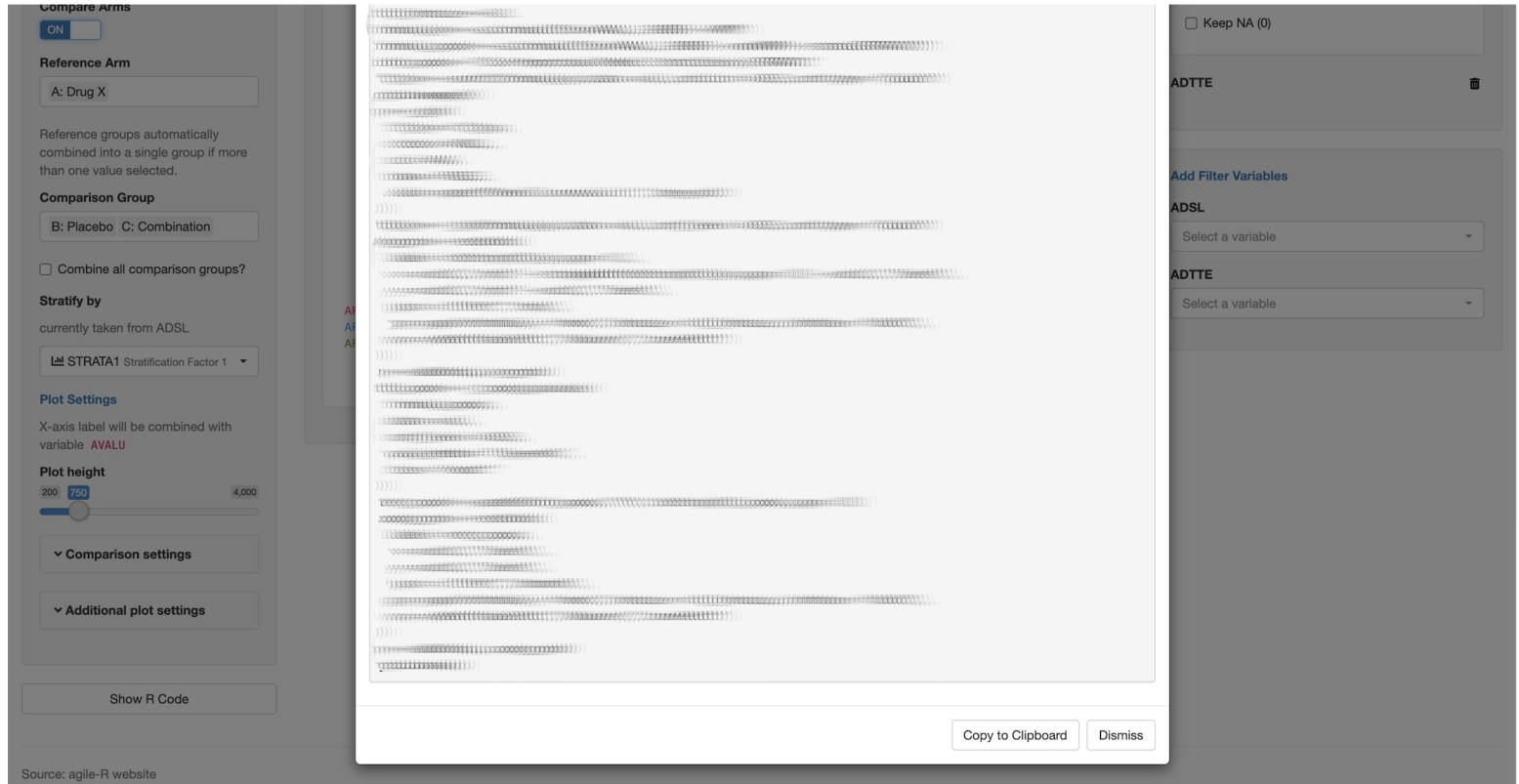


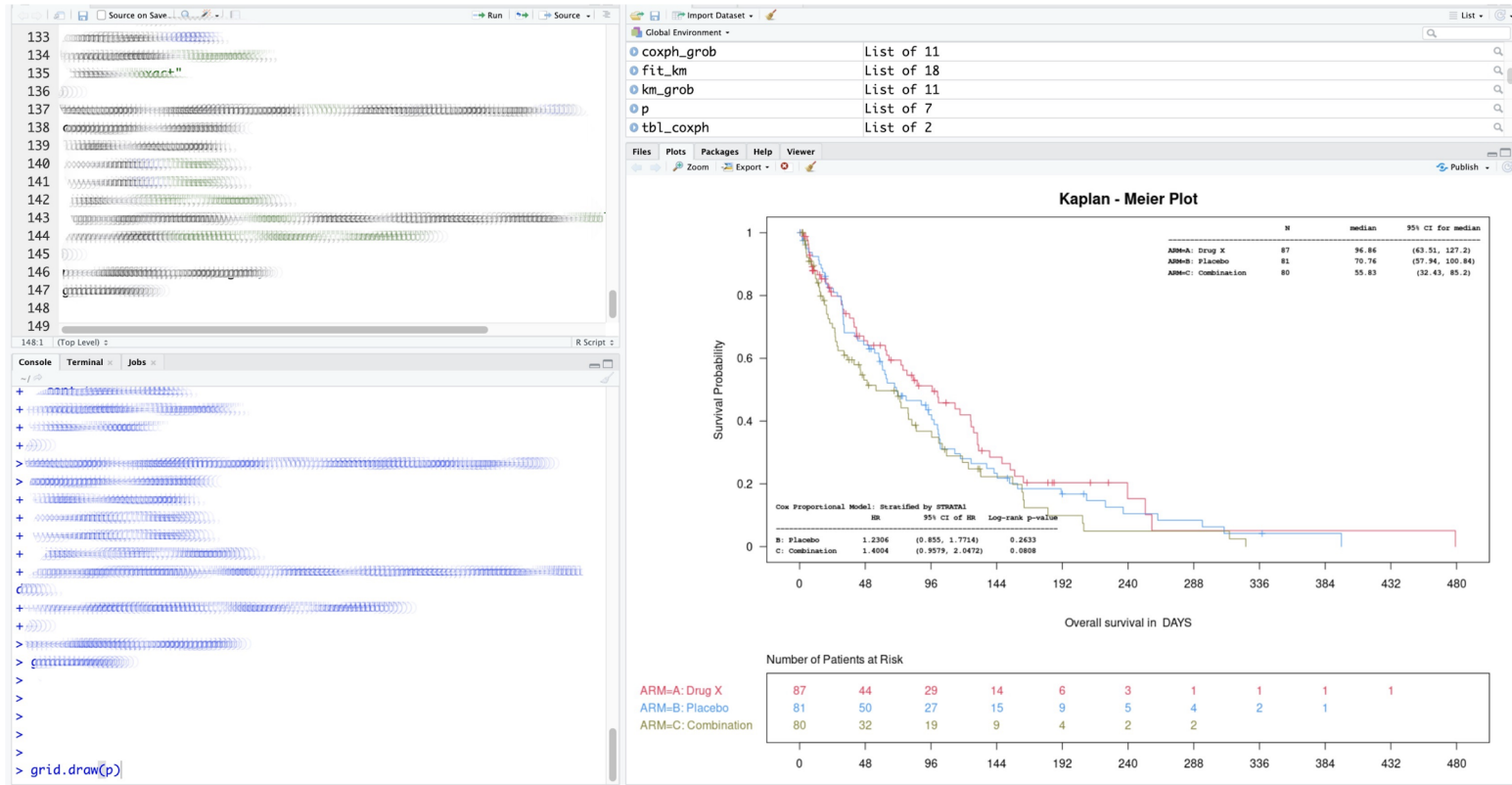
Clinical Trial data analysis: regulatory v. exploratory



Clinical Trial data analysis: regulatory v. exploratory







Innovations in Clinical Trial analysis

Visions for future

Clinical Trial data analysis: regulatory v. exploratory

Industry, HA collaboration and open sourcing

Industry, HA collaboration and open sourcing

Innovations in the dockerization and cloud computing spaces are providing an opportunity to challenge the way the submissions/study results are provided to the Health Authorities.

- Phuse working group *Best Practices for Interactive Analyses for Decision Making & Submissions* is working on the white paper how to leverage Visual Analytics in submissions to improve interactions between regulatory agencies and sponsors and to increase effectiveness review of submitted data and analyses [5](#)
- Interactive Analysis for Decision Making & Submissions - An update from PHUSE Data Visualization Project [6](#)

There is an innovative approach and two independent solutions is being tested:

- *Containerized APP*
- *Stand alone HTML interactive display*

5 - [https://www.phusewiki.org/wiki/index.php?title=Best Practices for Interactive Analyses for Decision Making %26 Submissions](https://www.phusewiki.org/wiki/index.php?title=Best_Practices_for_Interactive_Analyses_for_Decision_Making_%26_Submissions)

6- [https://www.lexjansen.com/phuse-us/2020/dv/DV13 ppt.pdf](https://www.lexjansen.com/phuse-us/2020/dv/DV13_ppt.pdf)

Industry, HA collaboration and open sourcing

Examples in R to encourage the across-pharma collaborations:

- github.com/Roche/rtables - please refer to the “*SD05 - A Novel Way of Creating Tables in R using the refactored rtables R package*”, Phuse EU Connect 2020
- github.com/gowerc/difdf - enabling comparison of data frames
- github.com/pharmaR/riskmetric - collection of risk metrics to evaluate the quality of R packages

Open source projects might help in building a trust around the packages commonly utilised across industry, possibly also lower the cost of validation activities.

Industry, HA collaboration and open sourcing

The current clinical trial results delivery based on the PDF [7](#) could be improved:

- **digital study result** - providing the interactive equivalent of study results
- **from interactivity to the code** - full reproducibility by generating the source code
- **end user flexibility** - flexibility in exploring the final, interim or exploratory analysis
- **no need of scope control** - delivering more study results in innovative way with less efforts
- **efficiency gain from collaboration** - open source code & collaboration
- **innovation in regulatory space** - interactive regulatory submissions
- **building a trust around open source projects ...**

Doing now what patients need next