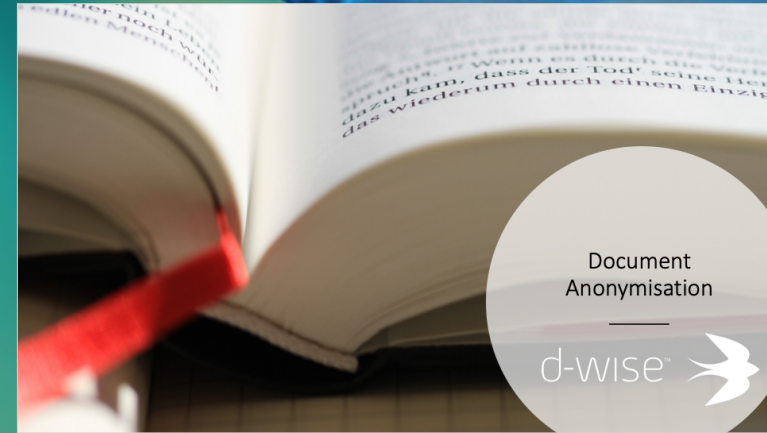


The background of the top section is an aerial photograph of a coastline, showing land and water in shades of green and blue. A large, white, stylized bird logo is positioned on the right side of the image, facing right. The logo has a long, pointed beak and a tail that splits into two curved sections.

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Accelerate to the Speed of Life

**Integrated Data & Document
Anonymisation for efficient data
sharing**





Understanding Risk

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What is a qualitative Risk Assessment?

- How Identifying is the information?
 - Highly
 - Somewhat
 - Unlikely
- How sensitive is the information?
 - Sensitive
 - Unsensitive

How identifying?	How sensitive?	Overall Risk
Unlikely	Unsensitive	Low
Somewhat	Unsensitive	Medium
Highly	Unsensitive	High
Unlikely	Sensitive	Medium
Somewhat	Sensitive	High
Highly	Sensitive	High

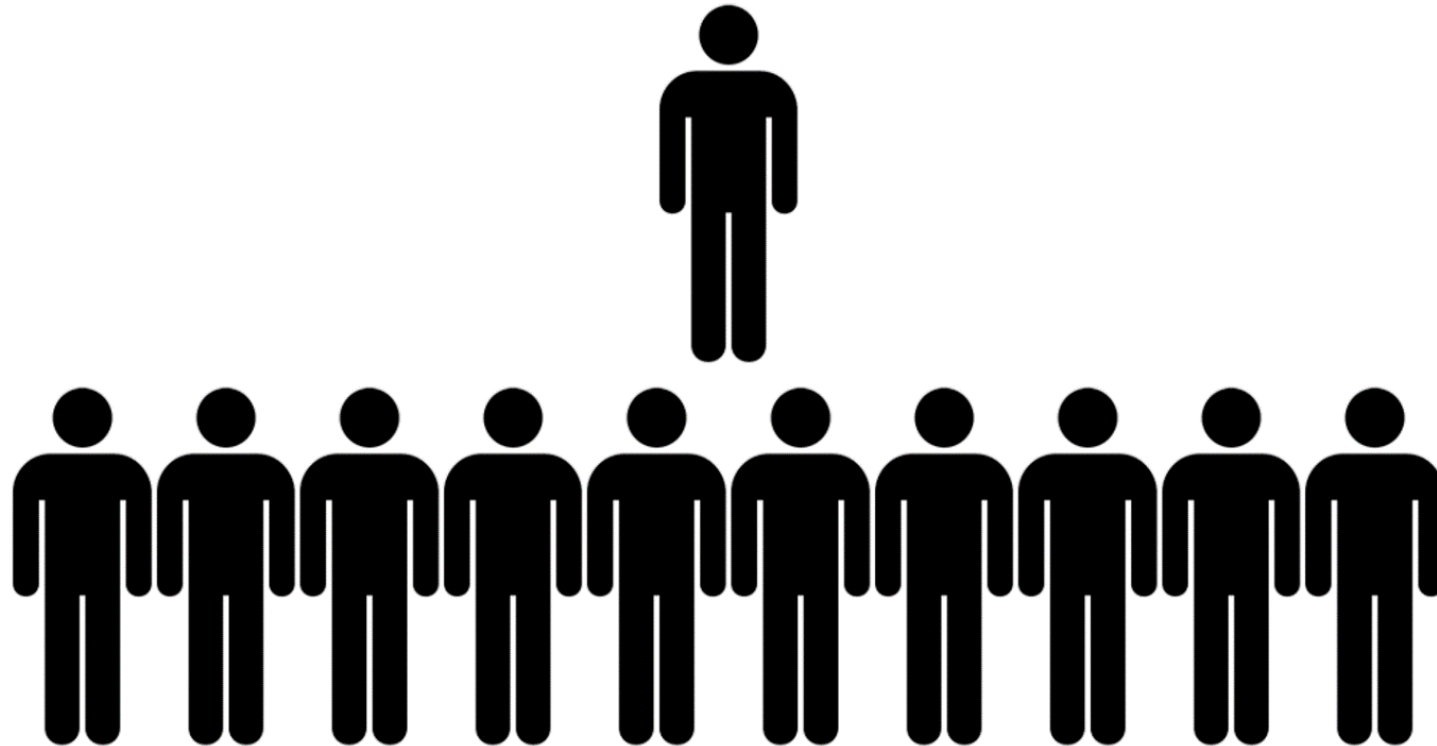
Risk Assessment Example

Subjid	Sex	Country	Brthdtc	INV Nam	Reason Discontinued
1001	M	USA	10/08/1979	Dr John Smith	Moved State
1002	M	USA	11/09/1984	Dr Emma Walls	Suicide Attempt
1007	F	USA	14/05/1983	Dr Harry Wilson	Miscarriage
1009	M	USA	10/06/1991	Dr John Smith	Patients wife called to say he was in car accident on 20 th October in Tarrytown
1023	M	USA	10/07/1990	Dr Stephen Strange	Death
1025	F	USA	12/12/1988	Dr Reed Richards	Lost contact with Patient
1038	F	USA	17/03/1977	Dr Bruce Banner	Martina's husband John called to say the medication is making her violent

Do you Understand your Risk?

Risk Threshold 0.09

Quantitative risk assessment





Population
Determination

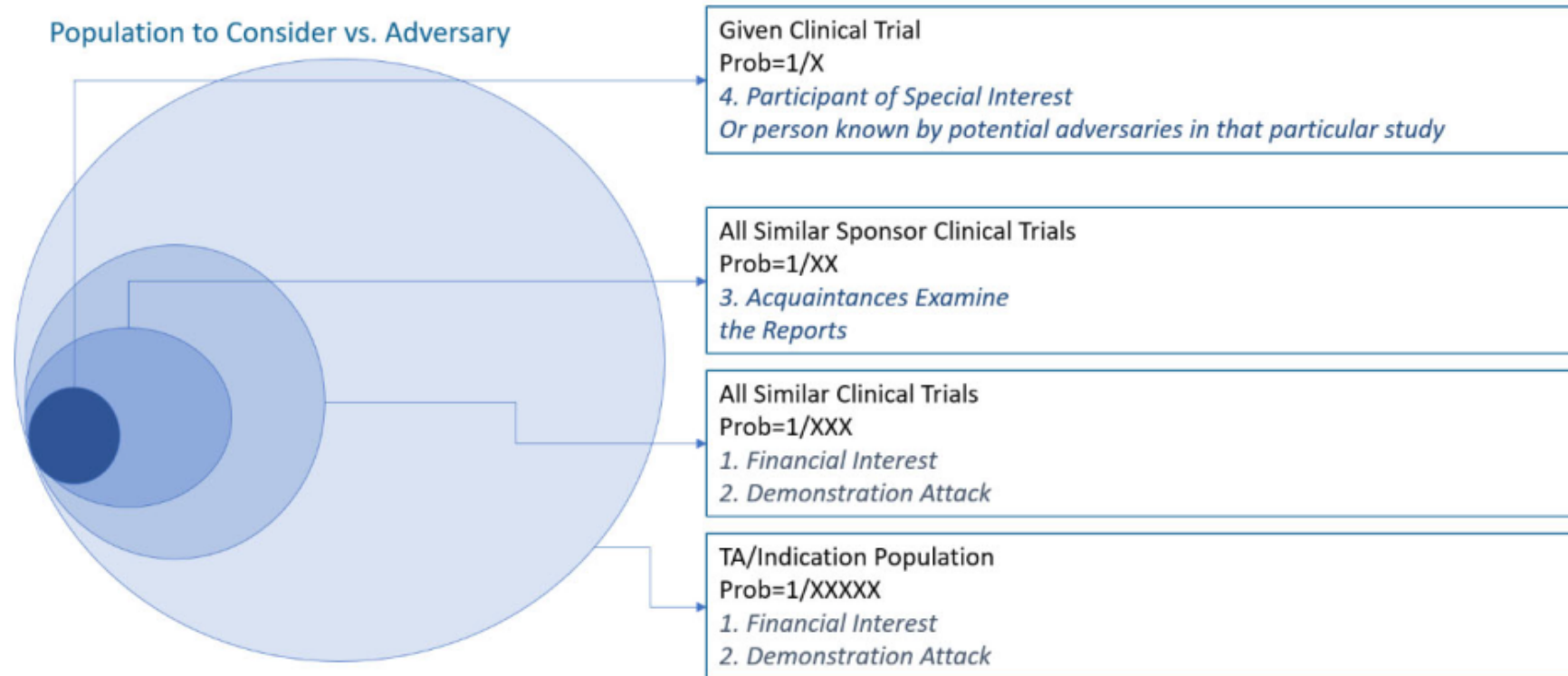
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Population determination

A larger population means more patients are going to share similar characteristics.

Achieving 9% Residual Risk

the candidate population given the context of disclosure and anticipated adversary





Data
Anonymisation

d-wise™



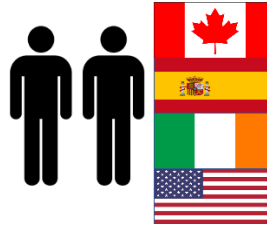
What is an identifier?



Sex



Age



Country



Height



Weight

- White
- Black
- Asian
- Pacific Islander

Race

- Hispanic
- Non-Hispanic

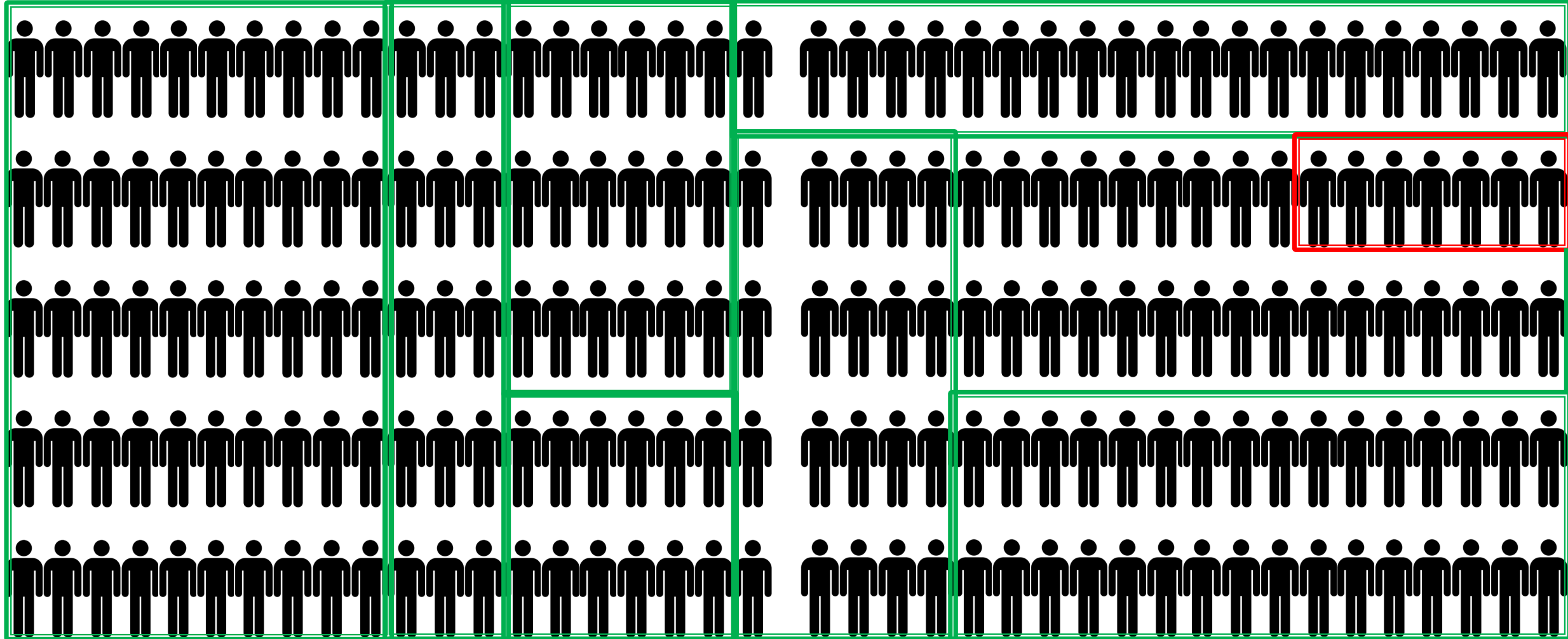
Ethnicity

- 17.4
- 19.9
- 27.2
- 35.4

BMI

Gender	Age	Country	Weight	Height	Race	Ethnicity	BMI
Male	40	Ireland	99KG	191cm	White	Non-Hispanic	27.1
Female	43	USA	68KG	172cm	White	Non-Hispanic	23
Male	44	USA	97KG	184cm	White	Hispanic	28.7
Male	38	Ireland	91KG	185cm	White	Non-Hispanic	26.6
Male	41	USA	107KG	194cm	Black	Non-Hispanic	28.4
Female	43	Ireland	77KG	184cm	White	Non-Hispanic	22.7
Male	43	USA	87KG	184cm	White	Non-Hispanic	28.7

Data Anonymisation



Data Anonymisation

SubjID	Sex	County	Age
1001	M	USA	21
1002	F	Spain	22
1003	M	USA	28
1004	F	USA	34
1005	F	Ireland	39
1006	F	USA	21
1007	M	USA	33
1008	M	Spain	34
1009	M	Ireland	25
1010	F	Ireland	25
1011	M	Ireland	26
1012	F	Spain	38
1013	M	Spain	37
1014	F	USA	37
1015	F	USA	22
1016	M	Spain	20
1017	M	Ireland	30
1018	F	Ireland	29
1019	M	USA	29
1020	F	Ireland	21
1021	M	Spain	27
1022	M	Spain	38
1023	M	Ireland	33
1024	M	USA	36
1025	F	USA	26

Data Anonymisation

SubjID	Sex	County	Age
1005	F	Ireland	30 to 39
1017	M	Ireland	30 to 39
1023	M	Ireland	30 to 39
1012	F	Spain	30 to 39
1008	M	Spain	30 to 39
1013	M	Spain	30 to 39
1022	M	Spain	30 to 39
1004	F	USA	30 to 39
1014	F	USA	30 to 39
1007	M	USA	30 to 39
1024	M	USA	30 to 39
1010	F	Ireland	20 to 29
1018	F	Ireland	20 to 29
1020	F	Ireland	20 to 29
1009	M	Ireland	20 to 29
1011	M	Ireland	20 to 29
1002	F	Spain	20 to 29
1016	M	Spain	20 to 29
1021	M	Spain	20 to 29
1006	F	USA	20 to 29
1015	F	USA	20 to 29
1025	F	USA	20 to 29
1001	M	USA	20 to 29
1003	M	USA	20 to 29
1019	M	USA	20 to 29

Data Anonymisation

SubjID	Sex	County	Age
1010	F	Europe	20 to 29
1018	F	Europe	20 to 29
1020	F	Europe	20 to 29
1002	F	Europe	20 to 29
1009	M	Europe	20 to 29
1011	M	Europe	20 to 29
1016	M	Europe	20 to 29
1021	M	Europe	20 to 29
1006	F	USA	20 to 29
1015	F	USA	20 to 29
1025	F	USA	20 to 29
1001	M	USA	20 to 29
1003	M	USA	20 to 29
1019	M	USA	20 to 29
1005	F	Europe	30 to 39
1012	F	Europe	30 to 39
1017	M	Europe	30 to 39
1023	M	Europe	30 to 39
1008	M	Europe	30 to 39
1013	M	Europe	30 to 39
1022	M	Europe	30 to 39
1004	F	USA	30 to 39
1014	F	USA	30 to 39
1007	M	USA	30 to 39
1024	M	USA	30 to 39



Anonymize (in progress)

PoSA: ? Threshold: 0.090

Tables

dm

<< My Tables

cm

dm

mh

Compare

Processed

Original

Frequencies

Show all

#	USUBJID	ACTARM	ACTARMCD	AGE	AGEU	ARM	ARMCD
1	01-225-1015	Placebo	Pbo	63	YEARS	Placebo	Pbo
	04-876-3091	***	Pbo	67	YEARS	Placebo	Pbo
2	01-225-1023	Placebo	Pbo	64	YEARS	Placebo	Pbo
	04-876-3052	***	Pbo	63	YEARS	Placebo	Pbo
3	01-225-1028	Xanomeline High Dose	Xan_Hi	71	YEARS	Xanomeline High Dose	Xan_Hi
	04-876-3053	Xanomeline High Dose	Xan_Hi	74	YEARS	Xanomeline High Dose	Xan_Hi
4	01-225-1033	Xanomeline Low Dose	Xan_Lo	74	YEARS	Xanomeline Low Dose	Xan_Lo
	04-876-3062	Xanomeline Low Dose	Xan_Lo	77	YEARS	Xanomeline Low Dose	Xan_Lo
5	01-225-1034	Xanomeline High Dose	Xan_Hi	77	YEARS	Xanomeline High Dose	Xan_Hi
	04-876-3064	Xanomeline High Dose	Xan_Hi	74	YEARS	Xanomeline High Dose	Xan_Hi
6	01-225-1047	Placebo	Pbo	85	YEARS	Placebo	Pbo
	04-876-3027	***	Pbo	89	YEARS	Placebo	Pbo
7	01-225-1057	Screen Failure	Scrnfail	59	YEARS	Screen Failure	Scrnfail
	04-876-3047	Screen Failure	Scrnfail	55	YEARS	Screen Failure	Scrnfail
8	01-225-1097	Xanomeline Low Dose	Xan_Lo	68	YEARS	Xanomeline Low Dose	Xan_Lo
	04-876-3037	Xanomeline Low Dose	Xan_Lo	67	YEARS	Xanomeline Low Dose	Xan_Lo
9	01-225-1111	Xanomeline Low Dose	Xan_Lo	81	YEARS	Xanomeline Low Dose	Xan_Lo
	04-876-3956	Xanomeline Low Dose	Xan_Lo	86	YEARS	Xanomeline Low Dose	Xan_Lo
10	01-225-1115	Xanomeline Low Dose	Xan_Lo	84	YEARS	Xanomeline Low Dose	Xan_Lo
	04-876-3958	Xanomeline Low Dose	Xan_Lo	89	YEARS	Xanomeline Low Dose	Xan_Lo
11	01-225-1118	Placebo	Pbo	52	YEARS	Placebo	Pbo
	04-876-3959	***	Pbo	53	YEARS	Placebo	Pbo

Data Sharing



sein Leben
hier noch wür-
allen Menschen

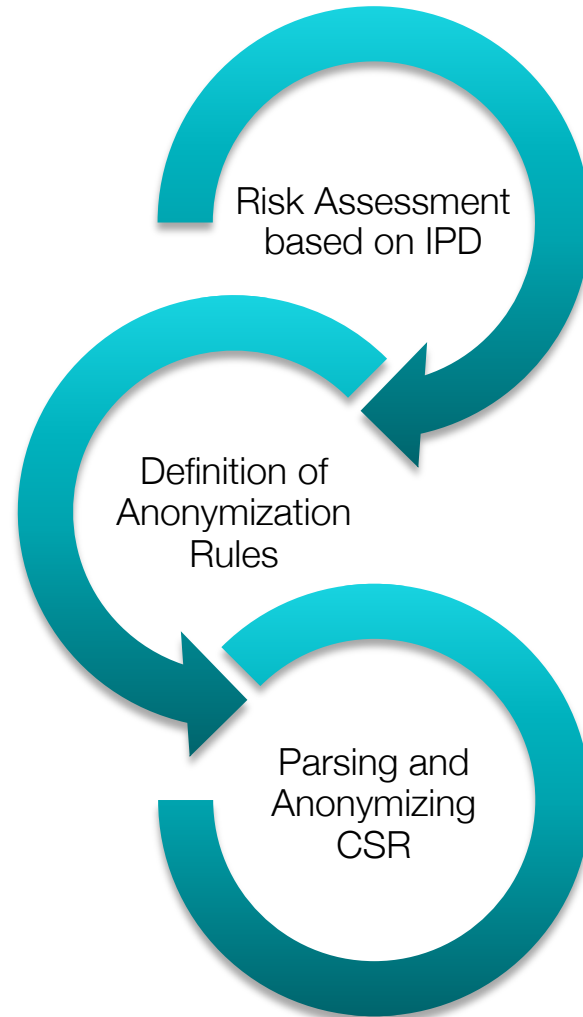
Wenn es durch die Ver-
spruch. 17 Wenn es durch die Ver-
dazu kam, dass der Tod^r seine Herr-
das wiederum durch einen Einzige

Document Anonymisation

d-wise™



Risk & CSR Anonymization



Document Anonymisation

Patient ABCD-123-12345 is a white female from Spain aged 36. She entered the trial on October 14, 2016. She was hospitalised on 18/11/1996 due to fatigue.

Patient ZYXW-098-09876 is a PPD PPD from Europe aged 33 PPD entered the trial on October 26, 2016 PPD was hospitalised on 30/11/1996 due to fatigue.

Drug Substance Xanomeline
Study Code CDISCPIL0T01
Edition Number 1.0
Date 31AUG2016
Table 12.2.1.2 Electronic narratives by patient - serious adverse events

PATIENT 01-225-1023
CASE 2012AP01234
TREATMENT: Placebo

DEATH :
WITHDRAWAL :
NON-FATAL SERIOUS AE : ATRIOVENTRICULAR BLOCK SECOND DEGREE
ALT/CK ELEVATION :

BASELINE INFORMATION:

AGE/SEX/RACE :64/M/WHITE
DAYS ON STUDY :90
RANDOMIZED/STARTED:2012-08-05 / 2012-08-05
STOPPED :2013-02-18 REASON FOR STOPPING: FINAL LAB VISIT
CURRENT ILLNESSES :FATIGUE, INFLUENZA, DIARRHOEA, CARPAL TUNNEL, DEPRESSION, HEADACHE
PAST ILLNESSES :MIGRAINE

DEATH INFORMATION: NA

DIED: NO POST-MORTEM: CAUSE OF DEATH MEDDRA:
ON/POST TREATMENT:

TREATMENT INFORMATION:

TREATMENT/ DOSE	DATE DOSE FIRST PRESCRIBED
Placebo	2012-08-05
Placebo	2012-08-05

Drug Substance Xanomeline
Study Code CDISCPIL0T01
Edition Number 1.0
Date 31AUG2016
Table 12.2.1.2 Electronic narratives by patient - serious adverse events

PATIENT 04-876-3052
CASE PPD
TREATMENT: Placebo

DEATH :
WITHDRAWAL :
NON-FATAL SERIOUS AE : ATRIOVENTRICULAR BLOCK SECOND DEGREE
ALT/CK ELEVATION :

BASELINE INFORMATION:

AGE/SEX/RACE :63/M/WHITE
DAYS ON STUDY :90
RANDOMIZED/STARTED:2012-08-15 / 2012-08-15
STOPPED :2013-02-28 REASON FOR STOPPING: FINAL LAB VISIT
CURRENT ILLNESSES :FATIGUE, INFLUENZA, DIARRHOEA, CARPAL TUNNEL, DEPRESSION, HEADACHE
PAST ILLNESSES :MIGRAINE

DEATH INFORMATION: NA

DIED: NO POST-MORTEM: CAUSE OF DEATH MEDDRA:
ON/POST TREATMENT:

TREATMENT INFORMATION:

TREATMENT/ DOSE	DATE DOSE FIRST PRESCRIBED
Placebo	2012-08-15
Placebo	2012-08-15

Document Sharing



Health
Canada

Santé
Canada

The background of the slide features a close-up photograph of a spider web covered in water droplets of various sizes. The droplets are glistening and reflect light, set against a warm, golden-brown background. A large, semi-transparent white circle is positioned on the right side of the slide, serving as a backdrop for the text and logo.

Integrated Data and Document Anonymisation

d-wise™





Anonymize (in progress)

PoSA: ? Threshold: 0.090

Tables

dm

<< My Tables

cm

dm

mh

Compare

Processed

Original

Frequencies

Show all

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	04-876-3958	Xanomeline Low Dose	Xan_Lo	89	YEARS	Xanomeline Low Dose	Xan_Lo
11	01-225-1118	Placebo	Pbo	52	YEARS	Placebo	Pbo
	04-876-3959	***	Pbo	53	YEARS	Placebo	Pbo

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DEATH :
WITHDRAWAL :
NON-FATAL SERIOUS AE : ATRIOVENTRICULAR BLOCK SECOND DEGREE
ALT/CK ELEVATION :

BASELINE INFORMATION:

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DEATH INFORMATION: NA

DIED: NO POST-MORTEM: CAUSE OF DEATH MEDDRA:
ON/POST TREATMENT:

TREATMENT INFORMATION:

TREATMENT/ DOSE	DATE DOSE FIRST PRESCRIBED
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TREATMENT INFORMATION:

TREATMENT/ DOSE	DATE DOSE FIRST PRESCRIBED
Placebo	2012-08-15
Placebo	2012-08-15

Integrated Data and Document Anonymisation

- Add value to anonymised artefacts
- Consistent “scrambling” through data and documents
- Greater use of anonymised data and documents for researchers
- Avoid risk of re-identifying by anonymising separately
- Integrate anonymisation and sharing into typical routine

CLINICAL TRIAL INNOVATORS

Clinical Trial Acceleration

- 16+ years heritage
- 78 life science clients
- Vendor independent
- +90% of top 20 modernizations
- Fully managed cloud/hosting services
+5000 managed users
- 20 fully managed private cloud clients



Clinical Trial Transparency

- 5 years
- 11 life science clients
- Blur: leading tool in quantifiable risk
& anonymization
- +30 policy 0070 submissions
- +5500 redacted documents



Health
Canada

