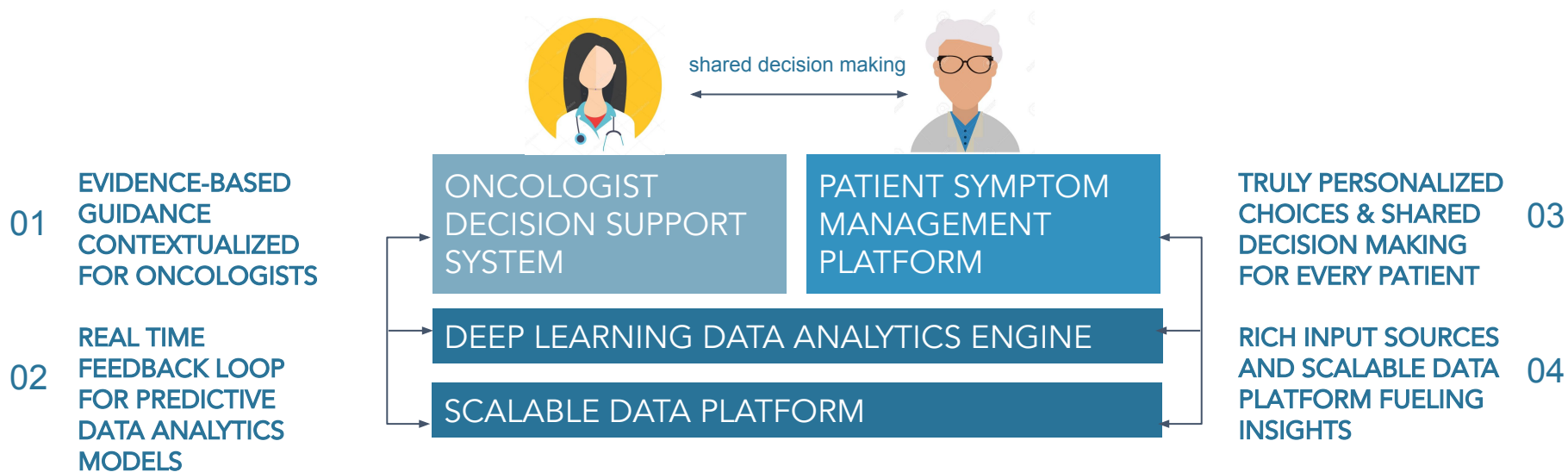


RŌNIN

Cancer intelligence for the N of 1

R-Ladies Meetup | Clara Oromendia | August 2019

WE'RE BUILDING A CANCER DECISION SUPPORT SYSTEM THAT DELIVERS INSIGHTS AND EFFICIENCIES AT THE POINT OF CARE



Source of Data: Clinical Trials



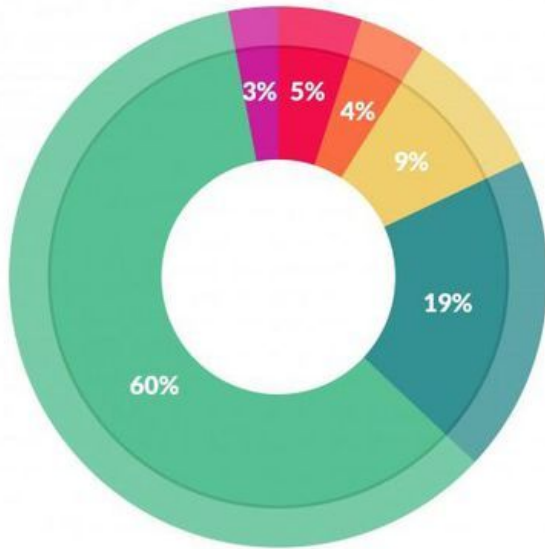
Many
variables,
few trials?

Few variables,
many **trials**?



The 80/20 data science dilemma

Most data scientists spend only 20 percent of their time on actual data analysis and 80 percent of their time finding, cleaning, and reorganizing huge amounts of data, which is an inefficient data strategy



What data scientists spend the most time doing

- Building training sets: 3%
- Cleaning and organizing data: 60%
- Collecting data sets: 19%
- Mining data for patterns: 9%
- Refining algorithms: 4%
- Other: 5%

Adverse Events Data

AstraZeneca Table

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	
1	RAW	STUDY	PART	LINE	VISIT	AEANY	AENO	AESER	AEACTIP	CTGMAX	AETREAT	AECAUDIS	AECAUS	AEOUTC	AEECODE	AEDTXT	PT_CODE	PT_NAME	
2	1	D432000015	A	1	NA	1	1	0	0	2	0		0	0	10047332	Vertebral collapse	10041541	Spinal compression fracture	
3	1	D432000015	A	1	NA	1	1	0	0	1	1		1	0	10002546	Ankle oedema	10030124	Oedema peripheral	
4	1	D432000015	A	2	NA	1	2	1	0	2	1		0	0	10069937	Joint prosthesis loosening	10064684	Device dislocation	
5	1	D432000015	A	1	NA	1	1	0	0	2	0		0	0	10054527	Paresthesia foot	10033775	Paresthesia	
6	1	D432000015	A	2	NA	1	2	1	0	3	0		0	0	1	10018336	Glioblastoma	10018336	Glioblastoma
7	1	D432000015	A	1	NA	1	2	0	0	1	0		0	1	10041955	Stasis dermatitis	10041955	Stasis dermatitis	
8	1	D432000015	A	2	NA	1	3	0	0	2	1		0	0	10017853	Gastritis	10017853	Gastritis	
9	1	D432000015	A	3	NA	1	4	0	3	2	0		1	0	10028372	Muscular weakness	10028372	Muscular weakness	
10	1	D432000015	A	4	NA	1	5	0	0	1	0		0	0	10062704	Localised rash	10037844	Rash	
11	1	D432000015	A	1	NA	1	1	0	0	1	1		0	1	10003988	Back pain	10003988	Back pain	
12	1	D432000015	A	1	NA	1	1	0	0	1	0	0	0	1	10015026	Epigastric pain	10000087	Abdominal pain upper	
13	1	D432000015	A	2	NA	1	2	0	0	1	1	0	1	0	10033446	Pain in leg	10033425	Pain in extremity	
14	1	D432000015	A	3	NA	1	3	0	0	1	1	0	1	0	10040617	Shoulder pain	10028391	Musculoskeletal pain	
15	1	D432000015	A	4	NA	1	4	0	0	1	1	0	0	1	10066973	Contrast media allergy	10066973	Contrast media allergy	
16	1	D432000015	A	5	NA	1	5	1	0	5	0	1	1	2	10047290	Ventricular fibrillation	10047290	Ventricular fibrillation	
17	1	D432000015	A	2	NA	1	2	0	0	1	0		1	0	10016256	Fatigue	10016256	Fatigue	
18	1	D432000015	A	1	NA	1	1	0	0	1	0		1	0	10019211	Headache	10019211	Headache	
19	1	D432000015	A	3	NA	1	3	0	0	1	1		1	1	10054791	Nycturia	10029446	Nocturia	
20	1	D432000015	A	4	NA	1	4	0	0	1	1		0	0	10024891	Low back pain	10003988	Back pain	
21	1	D432000015	A	5	NA	1	5	0	0	1	1		1	0	10019211	Headache	10019211	Headache	
22	1	D432000015	A	9	NA	1	14	0	0	1	0		1	0	10053280	Malleolus oedema	10030124	Oedema peripheral	
23	1	D432000015	A	6	NA	1	6	0	0	1	1		0	0	10006451	Bronchitis	10006451	Bronchitis	
24	1	D432000015	A	7	NA	1	7	0	0	1	1		0	0	10028735	Nasal congestion	10028735	Nasal congestion	
25	1	D432000015	A	8	NA	1	11	0	0	2	1		0	1	10013990	Dysuria	10013990	Dysuria	
26	1	D432000015	A	11	NA	1	16	0	0	1	0		0	0	10018867	Haematuria	10018867	Haematuria	
27	1	D432000015	A	10	NA	1	15	0	2	1	1		0	0	10046571	Urinary tract infection	10046571	Urinary tract infection	

Amgen Table

	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	GEOREGCD	TRTA	AGEY	SEX	RACE	RACECD	AEDECOD	AESTDY	AEENDY	AEDURD	AECONT	AETOXGR	AESER	AEREL	AEACTLST	AESDTH	AESLIFE
2	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Acquired phimosis	471	475	5		2	N	NOT RELATED	88	N	N
3	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Actinic keratosis	581	581	1		2	N	NOT RELATED	88	N	N
4	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Actinic keratosis	581	581	1		2	N	NOT RELATED	88	N	N
5	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Asthenia	187	NA	NA		2	N	RELATED	04,88	1	N
6	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Bladder neck obstruction	1050	1050	1		2	Y	NOT RELATED	88	N	N
7	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Cataract	1050	1050	1		1	N	NOT RELATED	88	N	N
8	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Cataract	915	925	11		1	N	NOT RELATED	88	N	N
9	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	229	NA	NA		1	N	NOT RELATED	1	N	N
10	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	250	NA	NA		1	N	NOT RELATED	1	N	N
11	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	132	141	10		1	N	NOT RELATED	88	N	N
12	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	132	141	10		1	N	NOT RELATED	88	N	N
13	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	776	784	9		1	N	NOT RELATED	1	N	N
14	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	132	147	16		1	N	NOT RELATED	88	N	N
15	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	229	NA	NA		1	N	NOT RELATED	1	N	N
16	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	229	NA	NA		1	N	NOT RELATED	1	N	N
17	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Contusion	132	147	16		1	N	NOT RELATED	88	N	N
18	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Dysphagia	186	NA	NA		2	N	NOT RELATED	88	N	N
19	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Fatigue	NA	386	NA		1	N	NOT RELATED	1	N	N
20	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Fatigue	NA	776	NA		1	N	NOT RELATED	1	N	N
21	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Fatigue	777	NA	NA	Y	2	N	NOT RELATED	1	N	N
22	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Gastroesophageal reflux disease	144	NA	NA	Y	1	N	NOT RELATED	3	N	N
23	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Haematoma	132	147	16		1	N	NOT RELATED	88	N	N
24	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Insomnia	420	NA	NA		1	N	NOT RELATED	1	N	N
25	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Laceration	132	141	10		1	N	NOT RELATED	88	N	N
26	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Laceration	132	141	10		1	N	NOT RELATED	88	N	N
27	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Laryngeal cancer	33	NA	NA	Y	4	Y	NOT RELATED	88	N	N
28	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Muscular oedema	925	962	38		1	N	NOT RELATED	3	N	N
29	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Muscle spasms	47	47	1		2	N	NOT RELATED	1	N	N
30	NA	Controlled Arm	86	M	WHITE OR CAUCASIAN	1	Muscle strain	1177	1179	3		1	N	NOT RELATED	3	N	N

Adverse Events Data

For each adverse event, we want only 5 things:

1. Patient
2. Day started
3. Day ended
4. Type of event
5. Severity grade

	patient	start_day	end_day	name	grade
1	A	10	12	headache	1
2	B	32	33	fatigue	3
3	C	7	27	nausea	2


Trial 1: Amgen

- ✓ Dataset contains all information
- ✓ Labels provide description

Need to calculate end day

```
{r}
# Import
dat_amgen_raw <- haven::read_sas("Prostat_Amgen_2006_155_aae.sas7bdat")
# Munge
dat_amgen_raw %>%
  select(SUBJID, AEDECOD, AESTDY, AEDURD, AESER, AETOXGR, AECONT) %>%
  mutate(end_day = AESTDY + AEDURD) %>%
  rename(patient = SUBJID,
         start_day = AESTDY,
         name = AEDECOD,
         grade = AETOXGR) ->
  dat_amgen

# Combine
dat_ideal %>%
  full_join(dat_amgen) ->
  dat_full
```

	patient	name	start_day	 end_day		grade	
	SUBJID Subject Identifier for the Study	AEDECOD Dictionary-Derived Term	AESTDY Study Day of Start of Adverse Event	AEDURD Duration of Event in Days	AESER Serious Event	AETOXGR Standard Toxicity Grade	AECON Adverse Event Outcome
1	001163	Acquired phimosis	471	5	N	02	
2	001163	Actinic keratosis	581	1	N	02	
3	001163	Actinic keratosis	581	1	N	02	
4	001163	Cataract	1050	1	N	01	
5	001163	Cataract	915	11	N	01	
6	001163	Cataract	122	10	N	01	

Trial 2: AstraZeneca

- ✓ Dataset contains all information
- ✓ Labels provide description

Need to filter to Adverse Events only

```
```{r}
Import
dat_astraZe_raw <- haven::read_sas("Prostat_AstraZe_2008_103_r_aevbb.sas7bdat")
Munge
dat_astraZe_raw %>%
 rename(patient = SUBJ,
 start_day = AESDYRND,
 end_day = AEEDYRND,
 name = PT_NAME,
 grade = CTCGMAX) %>%
 filter(AEEVNT01 == 0) %>%
 select(patient, start_day, end_day, name, grade) ->
 dat_astraZe

Combine
dat_ideal %>%
 full_join(dat_amgen) %>%
 full_join(dat_astraZe) ->
 dat_full
```
```

patient

start_day

end_day

name

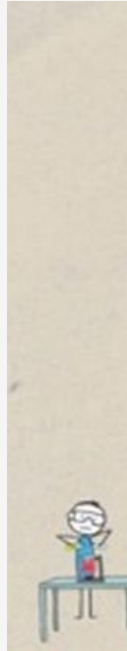
grade



| | SUBJ
Random patient identifier | AESDYRND
AE start study day - randomisation | AEEDYRND
AE end study day - randomisation | PT_NAME
MedDRA Preferred Term Name | CTCGMAX
Maximum CTC grade | AEEVNT01
Adverse Event |
|----|-----------------------------------|--|--|---------------------------------------|------------------------------|---------------------------|
| 39 | 359 | 68 | 88 | Urinary tract infection | 1 | 1 |
| 40 | 359 | 68 | 71 | Vomiting | 1 | 1 |
| 41 | 359 | 102 | NA | Insomnia | 1 | 1 |
| 42 | 359 | 145 | 206 | Tendonitis | 1 | 1 |
| 43 | 286 | 100 | 101 | Inguinal hernia | 3 | 1 |
| 44 | 45 | NA | NA | | | 0 |

Only 250 more trials to go!

(And 100 more variables)

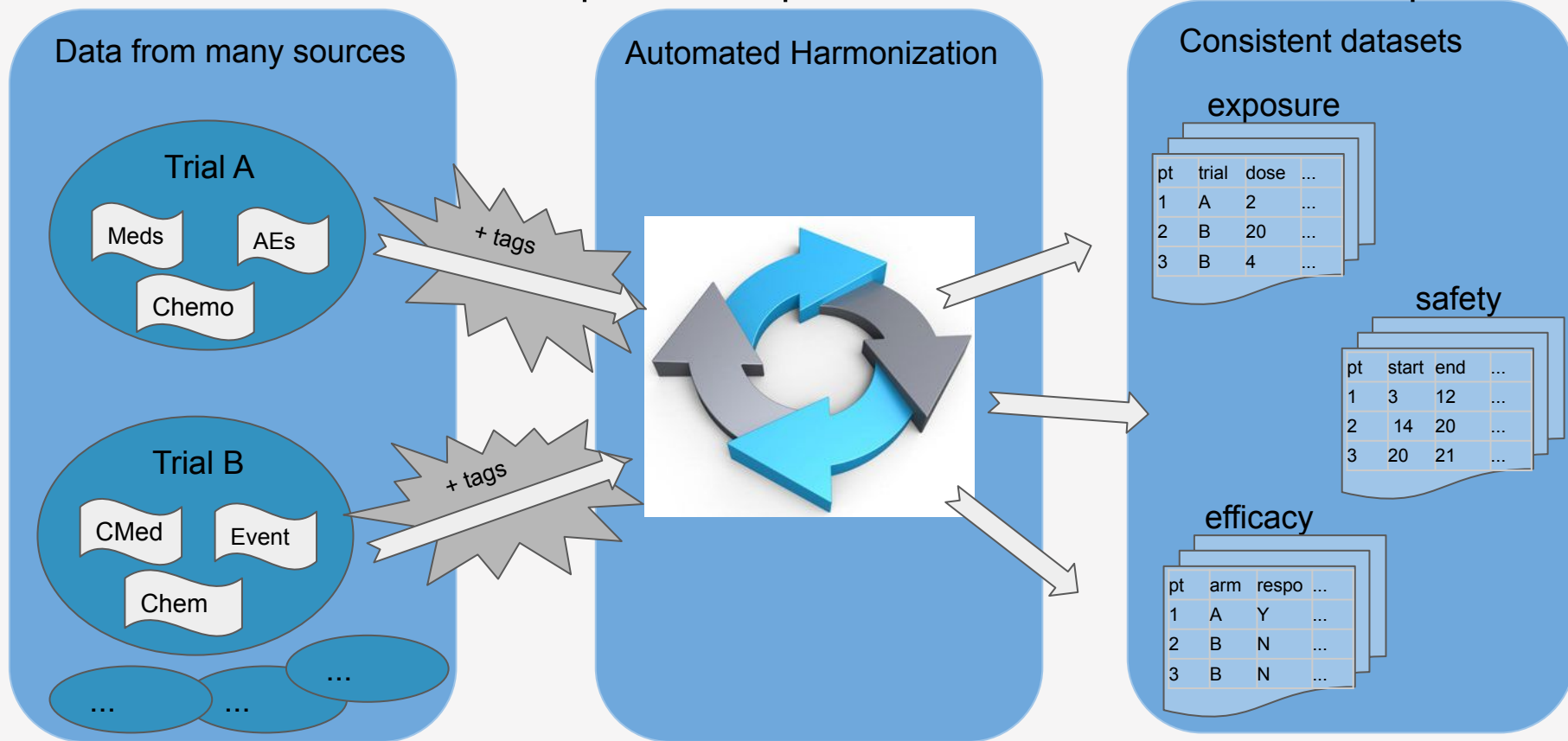


Banging my head vigorously against
my desk is surely
imminent.



your  cards
someecards.com

Time consuming & repetitive process -> find a better option



Better option: tagging

Amgen Meta

| name | label | class | tag | head | unique_vals |
|----------|-------------------------------------|-----------|-----------|------------------------------------|--------------------|
| STUDYID | Study Identifier | character | | 20050147 20050147 200501... | 20050147 |
| SUBJID | Subject Identifier for the Study | character | patient | 001163 001163 001163 0011... | 001163 00073... |
| GEOREG | Geographic Region | character | | NORTH AMERICA NORTH A... | NORTH AMERI... |
| GEOREGCD | Geographic Region Code | character | | NA NA NA NA NA NA | NA OT EU LA |
| TRTA | Actual Treatment Received | character | | Controlled Arm Controlled Ar... | Controlled Arm |
| AGEY | Age at Enrollment in Years | numeric | | 86 86 86 86 86 86 | 86 77 72 87 8... |
| SEX | Sex | character | | M M M M M M | M |
| RACE | Race | character | | WHITE OR CAUCASIAN WHIT... | WHITE OR CA... |
| RACECD | Race Code | character | | 01 01 01 01 01 | 01 02 03 88 04 |
| AEDECOD | Dictionary-Derived Term | character | name | Acquired phimosis Actinic ke... | Acquired phim... |
| AEBODSYS | Body System or Organ Class | character | | Reproductive system and bre... | Reproductive s... |
| AELLT | Adverse Event Low Level Term | character | | Paraphimosis Actinic keratosi... | Paraphimosis... |
| AEHLT | Adverse Event High Level Term | character | | Penile disorders NEC (excl er... | Penile disorder... |
| AEHLGT | Adverse Event High Level Group Term | character | | Penile and scrotal disorders (...) | Penile and scr... |
| AESTDY | Study Day of Start of Adverse Event | numeric | start_day | 471 581 581 187 NA 1050 | 471 581 187... |
| AEDURD | Duration of Event in Days | numeric | duration | 5 1 1 NA NA 1 | 5 1 NA 11 1... |
| AECONT | Adverse Event Continuing | character | | | Y |
| AETOXGR | Standard Toxicity Grade | character | grade | 02 02 02 02 02 01 | 02 01 04 03 05 |
| AESER | Serious Event | character | | N N N N Y N | N Y |
| AEREL | Causality | character | | NOT RELATED NOT RELATED... | NOT RELATED... |
| AEACTLST | List of Action Code | character | | 88 88 88 01 04,88 88 | 88 01 04,88 0... |
| AESDTH | Results in Death | character | | N N N N N N | N Y |
| AESLIFE | Is Life Threatening | character | | N N N N N N | N Y |

AstraZeneca Meta

| name | label | class | tag | head | unique_vals |
|----------|---------------------|-----------|-------------|-------------------------------|-----------------------------------|
| AESER | Serious AE | character | | 0 0 1 0 1 0 | 0 1 |
| SUBJ | Random patien... | numeric | patient | 252 265 265 407 407 455 | 252 265 407 455 522 61 29... |
| AEACTIP | Action Taken, I... | character | | 0 0 0 0 0 0 | 0 3 2 |
| CTCGMAX | Maximum CTC... | character | grade | 2 1 2 2 3 1 | 2 1 3 5 4 |
| AETREAT | Subject Recd T... | character | | 0 1 1 0 0 0 | 0 1 |
| AECAUDIS | AE Caused Su... | character | | | 0 1 |
| AECAUS | Reasonable Po... | character | | 0 1 0 0 0 0 | 0 1 |
| AEOUTC | AE Outcome | character | | 0 0 0 0 1 1 | 0 1 2 |
| AECODE | AE Code | character | | 10047332 10002546 100... | 10047332 10002546 100699... |
| AEDTXT | AE Dictionary T... | character | name | Vertebral collapse Ankle... | Vertebral collapse Ankle oed... |
| PT_CODE | MedDRA Prefe... | numeric | | 10041541 10030124 100... | 10041541 10030124 100646... |
| PT_NAME | MedDRA Prefe... | character | | Spinal compression fract... | Spinal compression fracture... |
| SOC_CODE | MedDRA Syste... | numeric | | 10022117 10018065 1001... | 10022117 10018065 100292... |
| SOC_NAME | MedDRA Syste... | character | | Injury, poisoning and pro... | Injury, poisoning and procedu... |
| SOC_ABRV | MedDRA Syste... | character | | Inj&P Genrl Genrl Nerv N... | Inj&P Genrl Nerv Neopl Skin... |
| HLGTCODE | MedDRA High... | numeric | | 10005942 10018073 100... | 10005942 10018073 100697... |
| HLGTNAME | MedDRA High... | character | | Bone and joint injuries Ge... | Bone and joint injuries Gener... |
| HLT_CODE | MedDRA High... | numeric | | 10041574 10030113 1006... | 10041574 10030113 1006979... |
| HLT_NAME | MedDRA High... | character | | Spinal fractures and dislo... | Spinal fractures and dislocati... |
| LLT_CODE | MedDRA Lowe... | numeric | | 10047332 10002546 100... | 10047332 10002546 100699... |
| LLT_NAME | MedDRA Lowe... | character | | Vertebral collapse Ankle... | Vertebral collapse Ankle oed... |
| MEDDRA_V | MedDRA Version | character | | 14.0 14.0 14.0 14.0 14.0 1... | 14 |
| AE_SFL | AE start relativ... | character | | D D D D A D | D A B |
| AE_EFL | AE end relative... | character | | D D D D | D A B |
| AEDUR | AE duration | character | | 13 days 27 days 35 days... | 13 days 27 days 35 days 84... |
| AEONSET | Onset after fir... | character | | 88 days 85 days 271 day... | 88 days 85 days 271 days 6... |
| AESIG | Other significa... | character | | 0 0 0 0 0 0 | 0 |
| AEDUR_D | AE duration (d... | numeric | | 13 27 35 84 NA NA | 13 27 35 84 NA 32 38 4... |
| AESDYLTR | AE start - last... | numeric | | -493 -331 -145 -217 22... | -493 -331 -145 -217 22... |
| POST28 | AE occurred >... | character | | 0 0 0 0 0 0 | 0 1 |
| AESDYTRT | AE start study... | numeric | | 88 85 271 6 244 32 | 88 85 271 6 244 32 5... |
| AEDYTRT | AE end study d... | numeric | | 100 111 305 89 NA NA | 100 111 305 89 NA 83 170 1... |
| AESDYRND | AE start study... | numeric | start_day | 89 86 272 7 245 33 | 89 86 272 7 245 33 5... |
| AEDYRND | AE end study d... | numeric | end_day | 101 112 306 90 NA NA | 101 112 306 90 NA 84 171 1... |
| AEVNT01 | Adverse Event | character | indic.num.1 | 1 1 1 1 1 1 | 1 0 |
| AEVNT02 | Causally Relate... | character | | 0 1 0 0 0 0 | 0 1 |
| AEVNT05 | Serious Advers... | character | | 0 0 1 0 1 0 | 0 1 |
| AEVNT06 | SAE Not Leadi... | character | | 0 0 1 0 1 0 | 0 1 |
| AEVNT07 | Causal SAE | character | | 0 0 0 0 0 0 | 0 1 |
| AEVNT10 | AE Leading to... | character | | 0 0 0 0 0 0 | 0 1 |

Better option: tagging

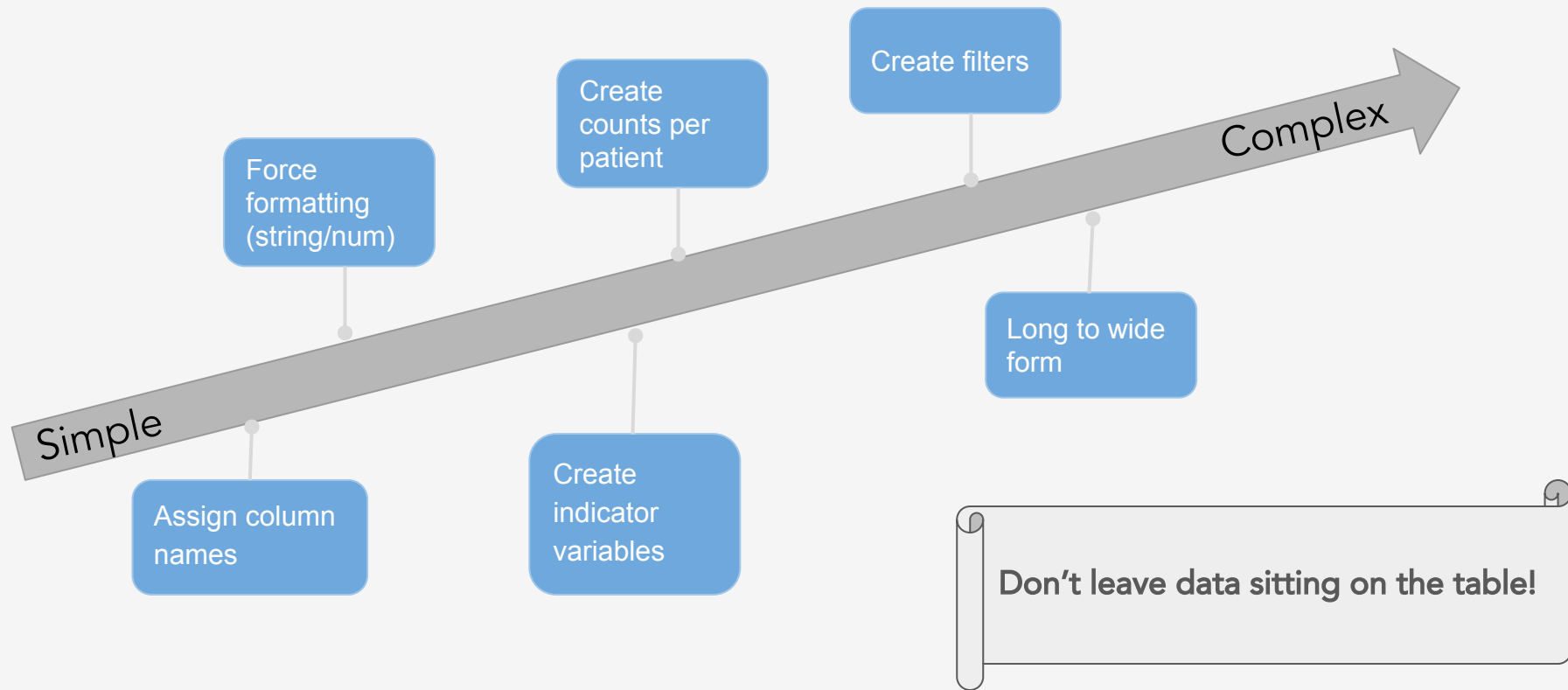
```
```{r}
Function to process tags
fn_standardize <- function(dat_raw, dat_meta){
 dat_raw = dat_raw[fn_applyFilters(dat_raw, dat_meta),]
 out = data.frame(patient = dat_raw[meta$name[which(meta$tag == "patient")]],
 start_day = dat_raw[meta$name[which(meta$tag == "start_day")]],
 name = dat_raw[meta$name[which(meta$tag == "name")]],
 grade = dat_raw[meta$name[which(meta$tag == "grade")]],
 patient = dat_raw[meta$name[which(meta$tag == "patient")]])
 if(any(meta$tag == "duration")) {
 out$end_day = out$start_day + start_day = dat_raw[meta$name[which(meta$tag == "duration")]]
 } else {
 out$end_day = dat_raw[meta$name[which(meta$tag == "end_day")]]
 }
 out
}

dat_amgen <- fn_standardize(dat_raw = haven::read_sas("Prostat_Amgen_2006_155_aae.sas7bdat"),
 dat_meta = read_csv(paste0("meta_", "Prostat_Amgen_2006_155_aae.sas7bdat", ".csv")))

dat_astraZe <- fn_standardize(dat_raw = haven::read_sas("Prostat_AstraZe_2008_103_r_aevbb.sas7bdat"),
 dat_meta = read_csv(paste0("meta_", "Prostat_AstraZe_2008_103_r_aevbb.sas7bdat", ".csv")))

Combine
dat_ideal %>%
 full_join(dat_amgen) %>%
 full_join(dat_astraZe) |>
 dat_full
```
```

Tag superpowers: Generalization



Better option: automatic tagging

Amgen Meta

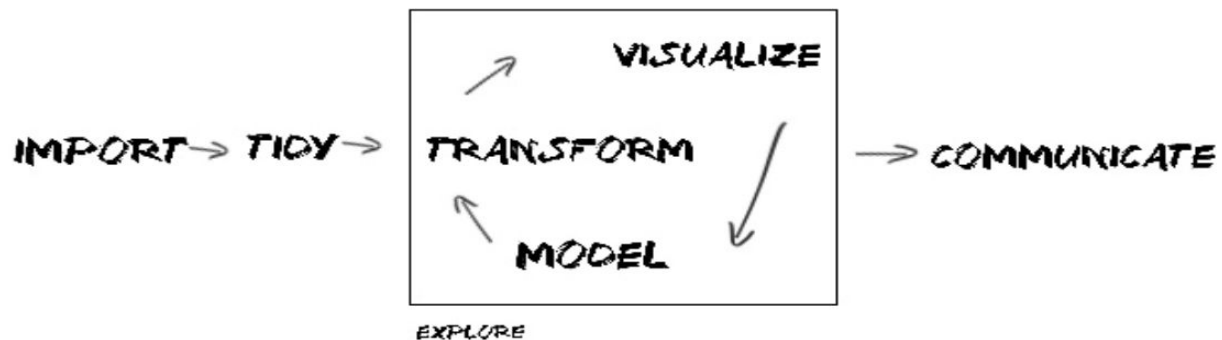
| meta_Prostat_Amgen_2006_155_aae.sas7bdat.csv | | | | | | |
|--|-------------------------------------|-----------|-----------|------------------------------------|--------------------|--|
| name | label | class | tag | head | unique_vals | |
| STUDYID | Study Identifier | character | | 20050147 20050147 200501... | 20050147 | |
| SUBJID | Subject Identifier for the Study | character | patient | 001163 001163 001163 0011... | 001163 00073... | |
| GEOREG | Geographic Region | character | | NORTH AMERICA NORTH A... | NORTH AMERI... | |
| GEOREGCD | Geographic Region Code | character | | NA NA NA NA NA NA | NA OT EU LA | |
| TRTA | Actual Treatment Received | character | | Controlled Arm Controlled Ar... | Controlled Arm | |
| AGEY | Age at Enrollment in Years | numeric | | 86 86 86 86 86 86 | 86 77 72 87 8... | |
| SEX | Sex | character | | M M M M M M | M | |
| RACE | Race | character | | WHITE OR CAUCASIAN WHIT... | WHITE OR CA... | |
| RACECD | Race Code | character | | 01 01 01 01 01 01 | 01 02 03 88 04 | |
| AEDECOD | Dictionary-Derived Term | character | name | Acquired phimosis Actinic ke... | Acquired phim... | |
| AEBODSYS | Body System or Organ Class | character | | Reproductive system and bre... | Reproductive s... | |
| AELLT | Adverse Event Low Level Term | character | | Paraphimosis Actinic keratosi... | Paraphimosis... | |
| AEHLT | Adverse Event High Level Term | character | | Penile disorders NEC (excl er... | Penile disorder... | |
| AEHLGT | Adverse Event High Level Group Term | character | | Penile and scrotal disorders (...) | Penile and scr... | |
| AESTDY | Study Day of Start of Adverse Event | numeric | start_day | 471 581 581 187 NA 1050 | 471 581 187... | |
| AEDURD | Duration of Event in Days | numeric | duration | 5 1 1 NA NA 1 | 5 1 NA 11 1... | |
| AECONT | Adverse Event Continuing | character | | | Y | |
| AETOXGR | Standard Toxicity Grade | character | grade | 02 02 02 02 02 01 | 02 01 04 03 05 | |
| AESER | Serious Event | character | | N N N N Y N | N Y | |
| AEREL | Causality | character | | NOT RELATED NOT RELATED... | NOT RELATED... | |
| AEACTLST | List of Action Code | character | | 88 88 88 01 04,88 88 | 88 01 04,88 0... | |
| AESDTH | Results in Death | character | | N N N N N N | N Y | |
| AESLIFE | Is Life Threatening | character | | N N N N N N | N Y | |

AstraZeneca Meta

| meta_Prostat_AstraZe_2008_103_r_aevbb.sas7bdat.csv | | | | | | |
|--|---------------------|-----------|-------------|-------------------------------|-----------------------------------|--|
| name | label | class | tag | head | unique_vals | |
| AESER | Serious AE | character | | 0 0 1 0 1 0 | 0 1 | |
| SUBJ | Random patien... | numeric | patient | 252 265 265 407 407 455 | 252 265 407 455 522 61 29... | |
| AEACTIP | Action Taken, I... | character | | 0 0 0 0 0 0 | 0 3 2 | |
| CTCGMAX | Maximum CTC... | character | grade | 2 1 2 2 3 1 | 2 1 3 5 4 | |
| AETREAT | Subject Recd T... | character | | 0 1 1 0 0 0 | 0 1 | |
| AECAUDIS | AE Caused Su... | character | | | 0 1 | |
| AECAUS | Reasonable Po... | character | | 0 1 0 0 0 0 | 0 1 | |
| AEOUTC | AE Outcome | character | | 0 0 0 0 1 1 | 0 1 2 | |
| AECODE | AE Code | character | | 10047332 10002546 100... | 10047332 10002546 100699... | |
| AEDTXT | AE Dictionary T... | character | name | Vertebral collapse Ankle... | Vertebral collapse Ankle oed... | |
| PT_CODE | MedDRA Prefe... | numeric | | 10041541 10030124 100... | 10041541 10030124 100646... | |
| PT_NAME | MedDRA Prefe... | character | | Spinal compression fract... | Spinal compression fracture... | |
| SOC_CODE | MedDRA Syste... | numeric | | 10022117 10018065 1001... | 10022117 10018065 100292... | |
| SOC_NAME | MedDRA Syste... | character | | Injury, poisoning and pro... | Injury, poisoning and procedu... | |
| SOC_ABRV | MedDRA Syste... | character | | Inj&P Genrl Genrl Nerv N... | Inj&P Genrl Nerv Neopl Skin... | |
| HLGTCODE | MedDRA High... | numeric | | 10005942 10018073 100... | 10005942 10018073 100697... | |
| HLGTNAME | MedDRA High... | character | | Bone and joint injuries Ge... | Bone and joint injuries Gener... | |
| HLT_CODE | MedDRA High... | numeric | | 10041574 10030113 1006... | 10041574 10030113 1006979... | |
| HLT_NAME | MedDRA High... | character | | Spinal fractures and dislo... | Spinal fractures and dislocati... | |
| LLT_CODE | MedDRA Lowe... | numeric | | 10047332 10002546 100... | 10047332 10002546 100699... | |
| LLT_NAME | MedDRA Lowe... | character | | Vertebral collapse Ankle... | Vertebral collapse Ankle oed... | |
| MEDDRA_V | MedDRA Version | character | | 14.0 14.0 14.0 14.0 14.0 1... | 14 | |
| AE_SFL | AE start relativ... | character | | D D D D A D | D A B | |
| AE_EFL | AE end relative... | character | | D D D D | D A B | |
| AEDUR | AE duration | character | | 13 days 27 days 35 days... | 13 days 27 days 35 days 84... | |
| AEONSET | Onset after fir... | character | | 88 days 85 days 271 day... | 88 days 85 days 271 days 6... | |
| AESIG | Other significa... | character | | 0 0 0 0 0 0 | 0 | |
| AEDUR_D | AE duration (d... | numeric | | 13 27 35 84 NA NA | 13 27 35 84 NA 32 38 4... | |
| AESDYLTR | AE start - last... | numeric | | -493 -331 -145 -217 22... | -493 -331 -145 -217 22... | |
| POST28 | AE occurred >... | character | | 0 0 0 0 0 0 | 0 1 | |
| AESDYTRT | AE start study... | numeric | | 88 85 271 6 244 32 | 88 85 271 6 244 32 5... | |
| AEDDYTRT | AE end study d... | numeric | | 100 111 305 89 NA NA | 100 111 305 89 NA 83 170 1... | |
| AESDYRND | AE start study... | numeric | start_day | 89 86 272 7 245 33 | 89 86 272 7 245 33 5... | |
| AEDYRND | AE end study d... | numeric | end_day | 101 112 306 90 NA NA | 101 112 306 90 NA 84 171 1... | |
| AEVNT01 | Adverse Event | character | indic.num.1 | 1 1 1 1 1 1 | 1 0 | |
| AEVNT02 | Causally Relate... | character | | 0 1 0 0 0 0 | 0 1 | |
| AEVNT05 | Serious Advers... | character | | 0 0 1 0 1 0 | 0 1 | |
| AEVNT06 | SAE Not Leadi... | character | | 0 0 1 0 1 0 | 0 1 | |
| AEVNT07 | Causal SAE | character | | 0 0 0 0 0 0 | 0 1 | |
| AEVNT10 | AE Leading to... | character | | 0 0 0 0 0 0 | 0 1 | |



@hspter



<https://r4ds.had.co.nz/explore-intro.html>

Thank you!

Stay in touch:



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