



PRO-ACT Database in ALS

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OUR MISSION
Make ALS Livable Until We Cure It



PRO-ACT (Pooled Resource Open-access ALS Clinical Trials) is the largest ALS trial dataset

- Started in 2014, Prize4Life (A. Kremer, N. Zach, M. Leitner, A. Sherman, M. Cudkowicz), partnership with NEALS, NCRI, ALS TDI and ALS Assoc.
- ALS is a heterogenous disease, both clinical and biological/molecular which makes predicting disease progression very challenging
- Prior to 2014, there were pooled datasets in MS and AD which had been instrumental in trial development
- Database would allow for “big data” collection from thousands of ALS patients to be data mined for predictions, trial design, outcome measures
- <https://pmc.ncbi.nlm.nih.gov/articles/PMC4239834/pdf/NEUROLOGY2013555987.pdf>;
https://pmc.ncbi.nlm.nih.gov/articles/PMC4404433/pdf/13311_2015_Article_336.pdf

PRO-ACT (<https://ncr1.partners.org/ProACT/Home/Index>)



Welcome to the
Pooled Resource Open-Access ALS Clinical Trials Database

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PRO-ACT provides users with easy access to:

- Over 12,200 fully anonymized subject records
- Placebo and treatment-arm data from 30 Phase II/III clinical trials
- Demographic, lab, medical and family history, and other data elements
- More than 16 million longitudinally collected data points

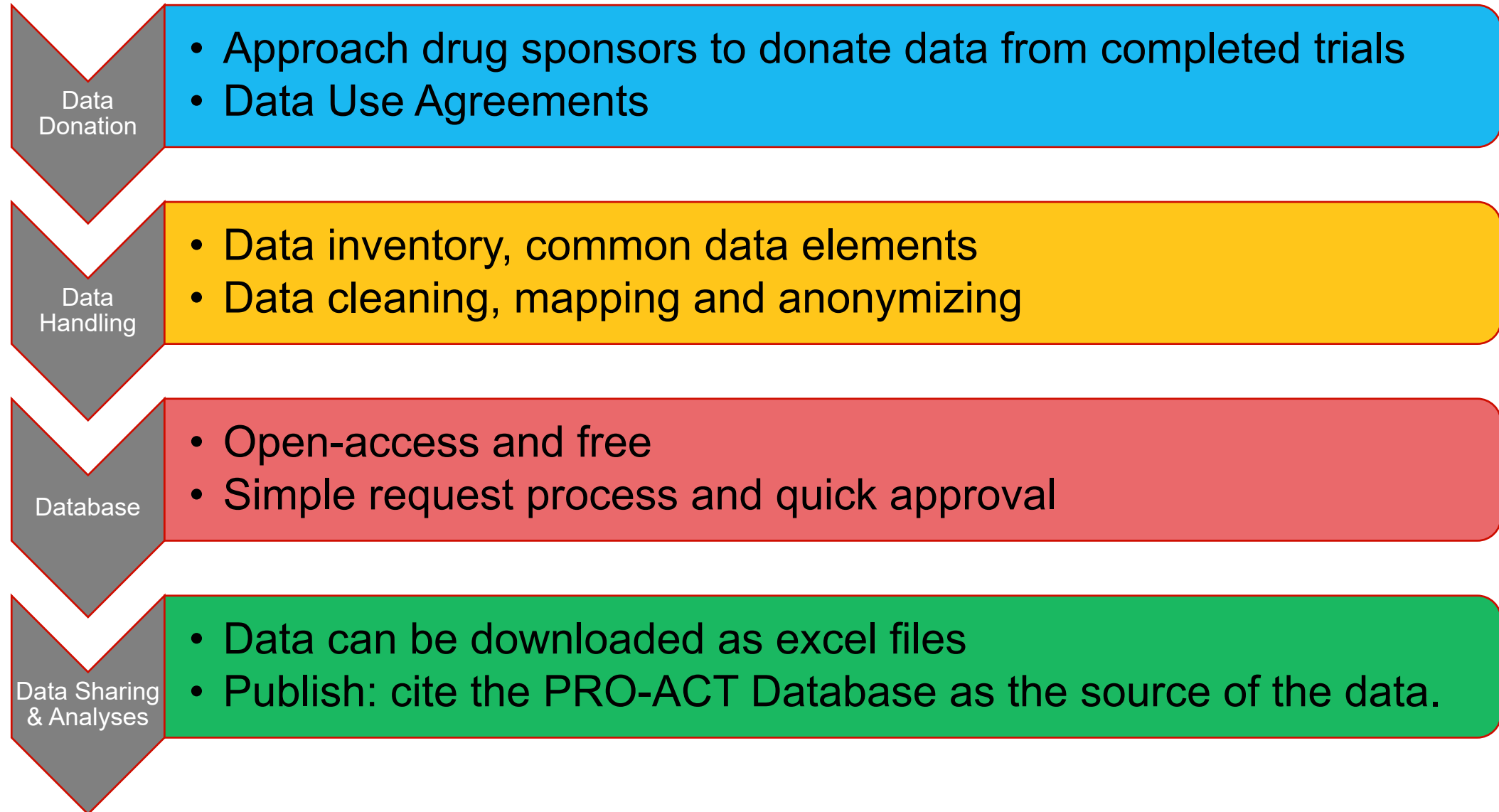
The popularity of the project is illustrated by the following statistics:

- Registered users: 2906
- Countries: 87
- Downloads: 19857

We thank everyone who has contributed to the creation of PRO-ACT including the companies, the researchers, and most of all the ALS patients, past and present, around the world, to whom the PRO-ACT initiative is dedicated:

- ALS Therapy Alliance
- Amylyx Pharmaceuticals, Inc.
- Cytokinetics, Inc.
- Knopp Biosciences
- Neuraltus Pharmaceuticals, Inc.
- Neurological Clinical Research Institute, Massachusetts General Hospital
- Northeast ALS Consortium
- Novartis
- Orion Corporation
- Prize4Life Israel
- Regeneron Pharmaceuticals, Inc.
- Sanofi
- Teva Pharmaceutical Industries, Ltd.
- The ALS Association

PRO-ACT Workflow



Collaboration with Pharma is the Key Driver!

- 12,229 fully anonymized-subject records
- Placebo and treatment-arm data from 32 Phase II/III clinical trials
- Demographic, labs, meds, medical and family history, and ALS outcomes
- More than 16 million longitudinal data points

- Registered users: 2,906
- Countries: 87
- Downloads: 19,857

DATA CONTRIBUTORS

- Amylyx Pharmaceuticals, Inc.
- Cytokinetics, Inc.
- Knopp Biosciences
- Neuraltus Pharmaceuticals, Inc.
- Neurological Clinical Research Institute @MGH
- Northeast ALS Consortium
- Novartis
- Orion Corporation
- Regeneron Pharmaceuticals, Inc.
- Sanofi
- Teva Pharmaceutical Industries, Ltd.

Data Sets

Please [register](#) to be able to download data.

In building PRO-ACT, as part of our data cleaning process for the lab data, units were converted,

Form Name	Subjects	Records	Values	Date/Time
Adverse Events	8799	76055	763571	7/29/2022 4:58:34 PM
ALL FORMS	11675	3369706	15515491	7/29/2022 5:00:55 PM
ALSFRS(R)	7712	67612	890345	8/1/2022 9:39:36 PM
Concomitant Medications	8521	125139	462288	8/1/2022 9:43:23 PM
Death report	4874	4875	8307	8/1/2022 9:46:06 PM
Demographics	11675	11675	44162	8/1/2022 9:46:51 PM
EI Escorial criteria	3416	3416	6832	8/1/2022 9:55:21 PM
Family History	1039	1103	2516	8/1/2022 9:56:34 PM
Forced Vital Capacity	9090	49110	202162	8/1/2022 9:57:22 PM
Handgrip Strength	1236	16274	144917	8/1/2022 9:59:09 PM
Laboratory Data	9280	2712589	10496429	8/1/2022 10:00:29 PM
Muscle Strength	1255	175461	1576452	8/1/2022 10:01:35 PM
Riluzole use	9478	9478	18934	8/1/2022 10:02:24 PM
Slow Vital Capacity	3501	15739	75183	8/1/2022 10:04:07 PM
Subject ALS History	10271	12936	39343	8/1/2022 9:41:23 PM
Treatment Group	9994	9994	17538	8/1/2022 10:04:43 PM
Vital Signs	10247	78250	766382	8/1/2022 10:05:27 PM

Impact of PRO-ACT on ALS R&D

Scientific Benefits:

- Started a new field in ALS research – Predictive Analytics
- Understanding of natural history and disease heterogeneity
- Novel biomarkers and pathways of disease
- Novel disease progression, survival, and staging models
- 90+ papers and 100+ symposia abstracts

Clinical Development Benefits

- Clinical Trial Simulations
- Test stratification theories
- Matching controls
- Reduce costs of future ALS clinical trials
- Explore link between disease progression and medication use
- FDA approval

Other Benefits

- Grow quantitative workforce with interest in/exposure to ALS data

