DON’T NEED IRB IN RIGHT TO TRY NEED ONE PERSON IN IRB TO APPROVE AT MINAMUM SOME IRB PROCESSES MAY BE DIFFERENT. IF NOT IRB NEED TO PAY FOR OUTSIDE IRB.

-Look at rate of irb approvals in mount Sinai system that is the paper. If we can use warehouse data or irb logs we can provide an element not really analyzed.

Title: Comparative analysis of treatment options available through the right to try legislation and the expanded access program.

Introduction:

Expanded access approval rate from Pfizer was 98% https://www.pfizer.com/purpose/medicine-access/compassionate-use.

Methods:

Using the Drugs@FDA database I opened the products.txt file through pandas to create a dataframe. Using that generated dataframe I created a list of all unique DrugNames. This gave me a collection of 7088 drugs that the FDA has approved. Then through the clinical trials database I downloaded all drugs listed in interventions for both trails listed as phase 3 that have statuses of either: not yet recruiting, recruiting, enroll by invitation, active not recruiting or suspended (but not including completed) and trails listed as available and/or approved for marketing in their expanded access program. From both these lists I found all unique drug entries and removed all those in the approved drugs@FDA database and those with the text phrase placebo. Because these databases are not linked it’s possible that this does not remove all the approved drugs to contain just the experimental drugs. However, this still provides value as an estimate of what is available.

Using PharmaGKB I downloaded a comprehensive drugs database. From this I created a python program that allowed for me to easily parse their database and query all drugs from Id’s, all Id’s from each drug and all the different terms used for each drug. This was done to create a more compressive list of all terms used for each drug such that one can quickly determine if a drug listed in the warehouse is novel or simply not the main name.

Results:

Discussion:

<https://www.ajmc.com/journals/evidence-based-oncology/2018/patient-centered-oncology-care-2017/weighing-the-merits-of-righttotry-laws-and-fdas-expanded-access-program>

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very similar to what I’m doing

<https://jech.bmj.com/content/jech/72/7/557.full.pdf> - high level impact on expanded acess

<http://journals.sagepub.com/doi/abs/10.1177/2168479018759661> - talks about IRB’s very valuable (analyzed data set of 100 irb’s to see what it took(

Could be intressting to explore impact of one IRB member review policy

Could be cool to search through 100 irb’s with nlp

OOOO could hit up mount Sinai irb to see if we could review their records of drug access and from there acess the acceptance rate. This is novel because no estimates of this number exists.

Possible we could bypass this through looking at patient info in data warehouse

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2684626> - shows a lot of drugs in expanded acess program get approved soon after

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2684626> - very similar to what we were doing originally looking at the approved drugs in drugs@fda and those in expanded acess in clincialtrials. They simply used this info to provide a timeframe about how long it took from expanded access to approval. Coolest thing is they used the expanded access flag as if it had value which we stated didn’t.

[**https://www.nature.com/articles/nbt0418-294**](https://www.nature.com/articles/nbt0418-294) **- nothing really intressting**

[**https://www.tandfonline.com/doi/pdf/10.1080/13543784.2018.1430137?needAccess=true**](https://www.tandfonline.com/doi/pdf/10.1080/13543784.2018.1430137?needAccess=true)

**-good sources descriptions**

Federal Right-to-Try Legislation — Threatening the FDA’s Public Health Mission Steven Joffe, M.D., M.P.H., and Holly Fernandez Lynch, J.D., M.B.E

-most famous paper on topic probs

[**https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5821240/**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5821240/)

**-right to try v v bad**

[**https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2669909**](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2669909)

**-righ try bad**