



# Can Current Adverse Drug Event (ADE) Reporting Systems Help to Reduce ADE?

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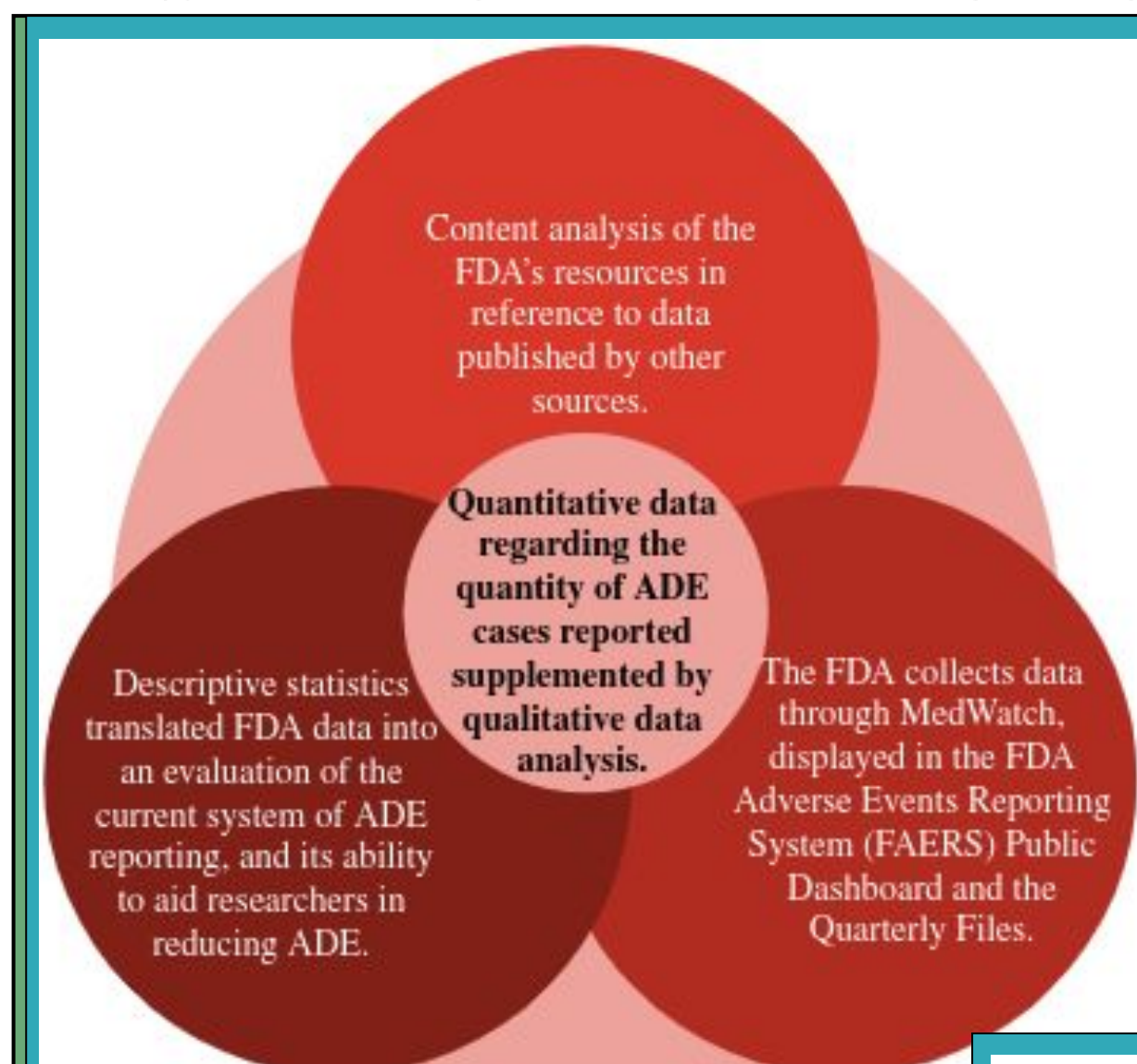
## INTRODUCTION

Medications are ubiquitous; however, medications can yield negative results. An **adverse drug event (ADE)** is any negative patient reaction during the duration of their drug intake, regardless of whether there is a proven cause-and-effect relationship. An **adverse drug reaction (ADR)**, a subset of ADE in which the patient imbibes the prescribed quantity of a particular drug, is a preventable case in which abuse or other such variables of the drug is not involved. (Schatz, Weber 2015) A 1994 study predicted ADR caused **106,000 deaths annually** (J, B, PN 1988). Proper reporting can help researchers **identify potential causes of ADEs**, allowing for greater ability to treat ADR and ADE, saving lives and money.

**1,255,936**

Domestic ADE reports ([ADE report data], 2017)

## RESEARCH METHODOLOGIES



1. Content Analysis of FAERS Reports
2. Generation of Graphs
3. Evaluate quality of FAERS and ability of FAERS to reduce ADE using graphs and descriptive statistics



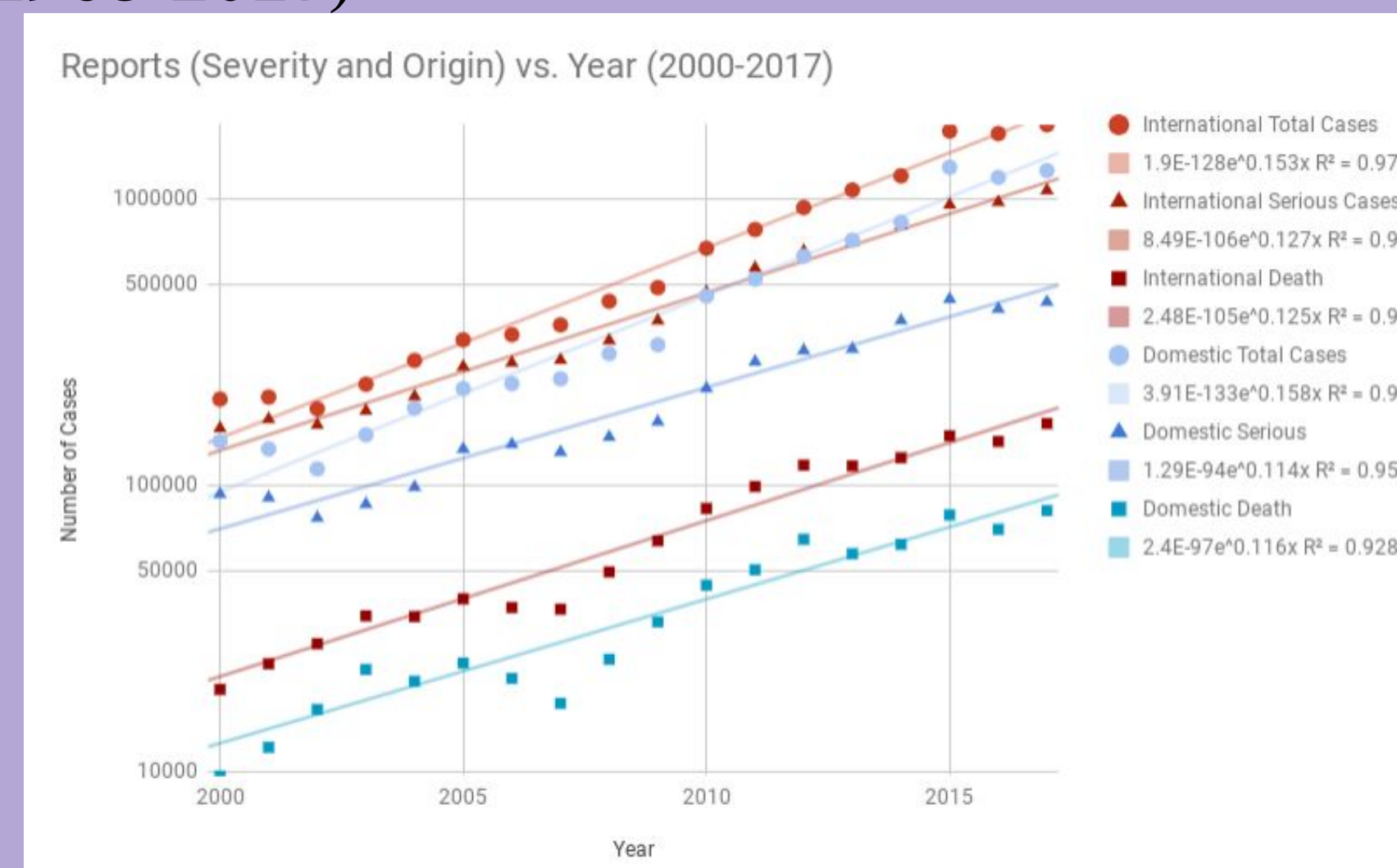
## DATA AND FINDINGS

Year	Number of Reports of ADE					
	Global Reports			Domestic (United States) Reports		
	Total Cases	Serious Cases	Death	Total Cases	Serious	Death
2017	1815738	1071193	164252	1255936	436786	81563
2016	1691978	974418	142139	1189162	413053	70102
2015	1727558	953991	148779	1290154	446802	78701
2014	1204050	807683	124,751	828069	376213	62151
2013	1074617	707415	116827	717861	299251	57615
2012	933122	656979	117532	631141	295313	64711
2011	782107	573888	98942	524773	269964	50634
2010	672497	472643	82955	458020	217882	44736
2009	490045	375897	63926	309397	166624	33294
2008	439169	320383	49765	288009	147356	24649
2007	363171	273834	36878	235305	130517	17294
2006	335633	267766	37373	226468	138992	21139
2005	321840	259612	40079	217484	133863	23904
2004	272825	204260	34757	185713	98480	20658
2003	225247	181835	34954	149983	85870	22708
2002	184892	162494	27935	114012	76920	16467
2001	203230	170079	23779	133854	90483	12142
2000	199822	158122	19341	142442	93115	9629

	Total Reports	Serious Reports	Death Reports	Serious (Percentage of Total Reports)	Death (Percentage of Total Reports)
Domestic (Total Reports)	10579082	4971610	789673	46.99472034%	7.464475651%
International (Total Reports)	14840598	8434750	1491711	56.83564773%	10.05155587%

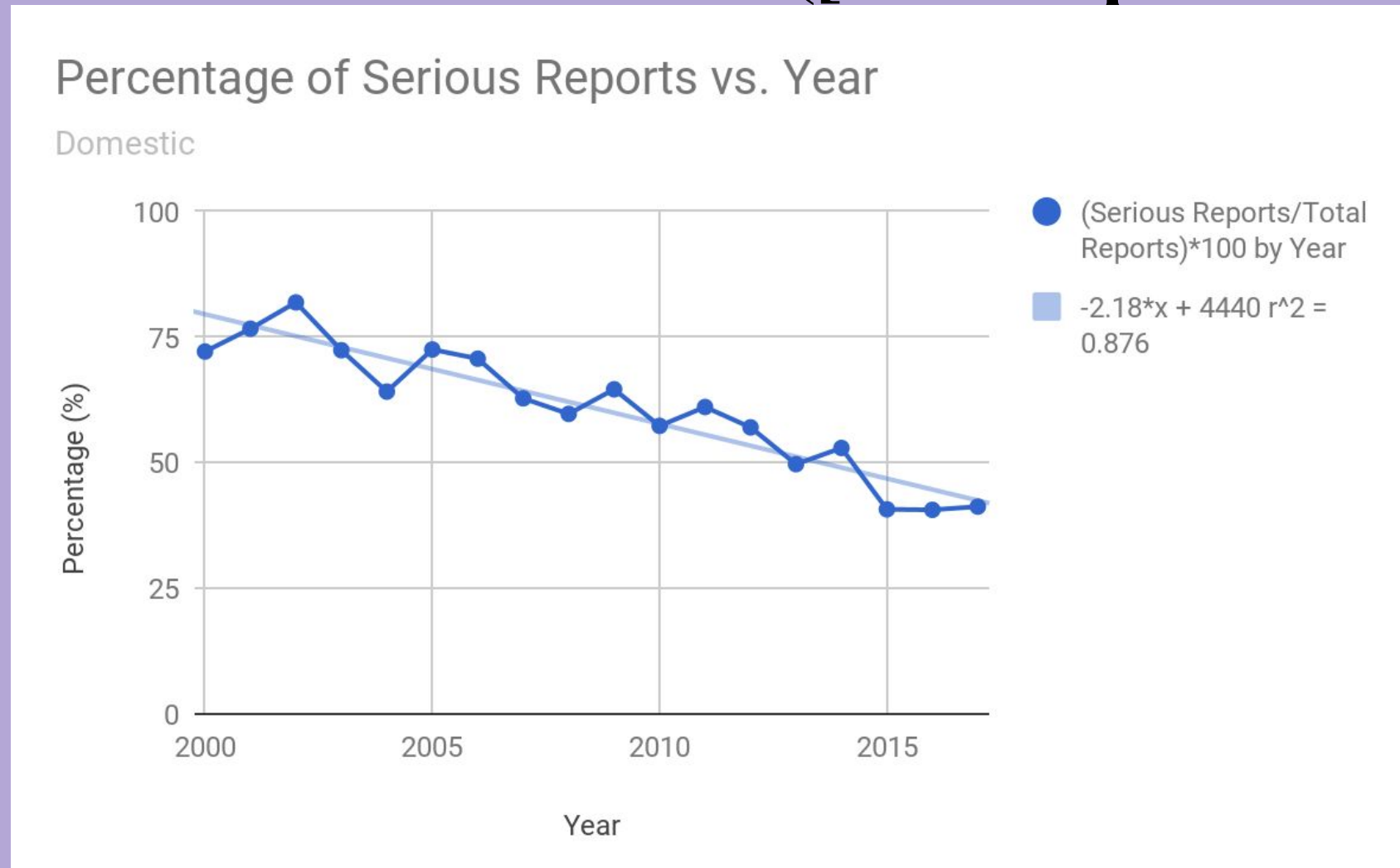
## DISCUSSION, ANALYSIS, AND EVALUATION

Figure 1: Overall Conclusions regarding Domestic Data ([ADE report data] 1968-2017)



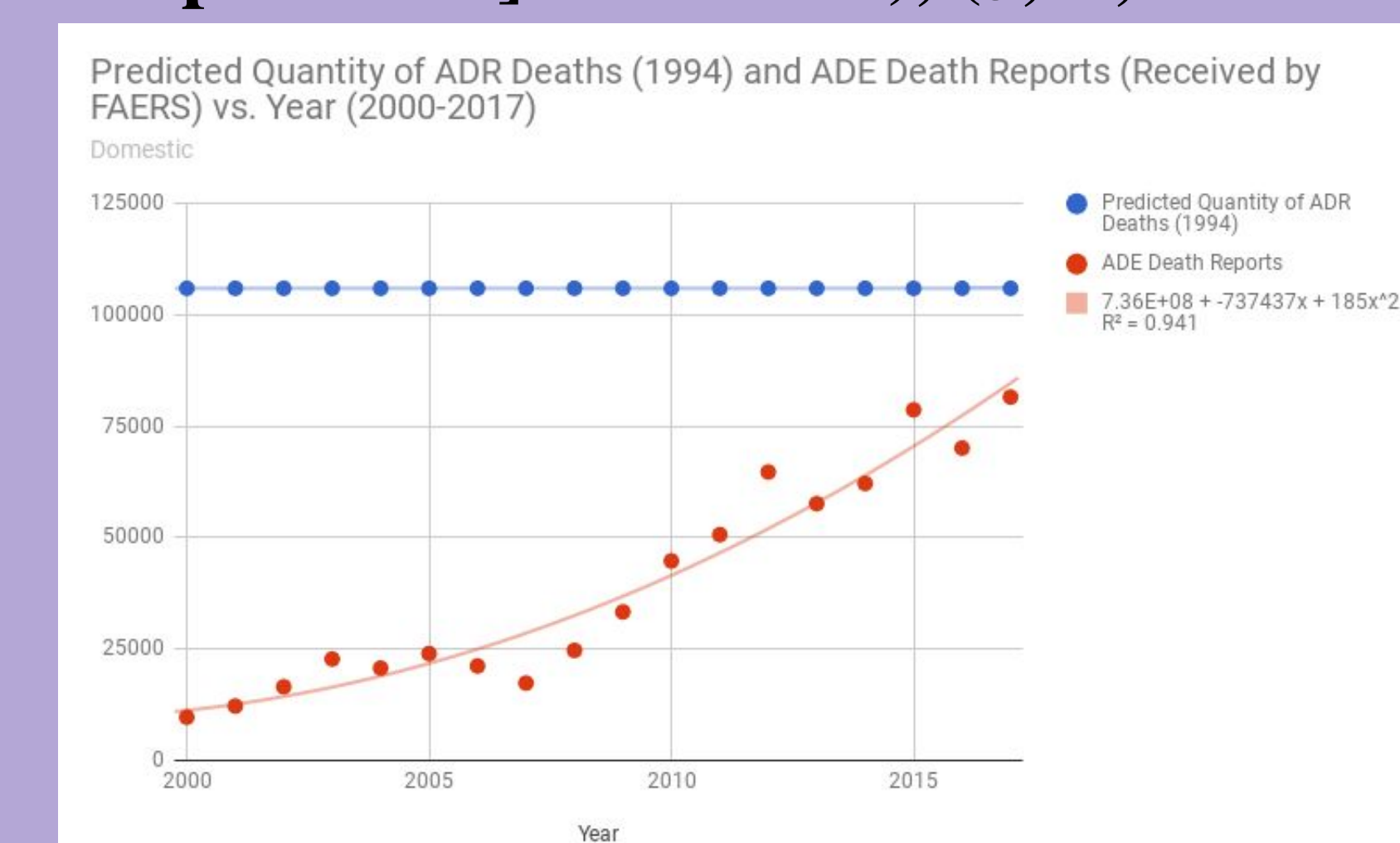
- The number of reports has increased exponentially from 2000 to 2017. As people imbibe more medications or health care professionals become more able to identify ADEs, more ADEs are reported.
- The quantity of serious reports, depending on filter, can be less subject to the fluctuations than the total number of reports.
  - Greater severity of symptoms would likely increase the ability to correctly diagnose patients with an ADE.
- A high percentage of reports comes from the United States.

Figure 2: Serious vs. Non-Serious ([ADE report data] 1968-2017)



- The percentage of total reports that are serious or fatal has decreased by approximately 2.18% each year.
- More conclusions may be drawn from the graph once the number of total reports begins to follow a logistic pattern, which it will have to do eventually.

Figure 3: FAERS Death Reports Collected vs. Predictions of ADR Deaths ([ADE report data] 1968-2017), (J, B, PN 1988)



- Currently, the FAERS Public Dashboard data does not successfully reflect the quantity of deaths in the United States, indicating either the reporting system or the prediction is likely inaccurate.

## CONCLUSIONS, IMPLICATIONS, AND NEXT STEPS

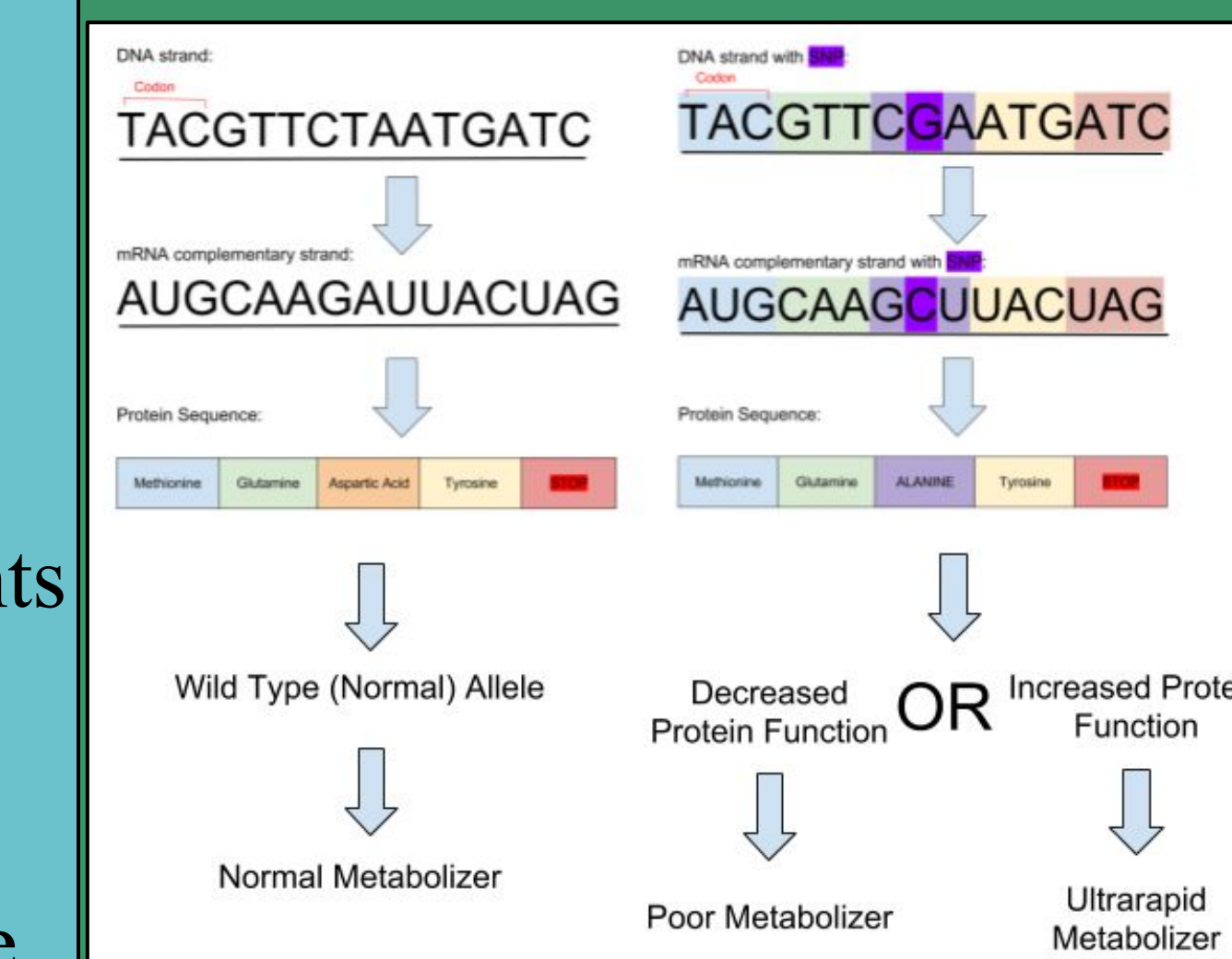
### Conclusions and Implications:

- As of now, the FAERS data provides inconclusive data and therefore is not an effective resource for the identification of cause of the drug reaction, especially as a system to identify potential drugs to test for genetic involvement in the ADE case.
- There are duplicate reports due to the mandated reporting of manufacturers in addition to healthcare personnel and consumers.
- Data does not reflect predicted trends.
- There is a rise in the number of total and serious reports
  - This may indicate...
    - an increasing ability to detect and identify ADEs
    - an increasing willingness to diagnose or report
    - a changing definition of an ADE
- This increase when coupled with the decrease in percentage of serious reports indicates improvement in willingness to report.

### Next Steps:

- Potential changes that could be made to improve the quality of the FDA's current reporting system
  - Inclusion of quantity of people on each medication
  - System to verify reports
  - Separate ADE and ADR reporting systems
  - Genetic information of patients
    - Could be inferred through alternative information
  - Media campaign to encourage increased reporting to the FDA and communication between reporters to reduce double reporting.

### What are SNPs?



Pharmacogenomics uses genetic variation to tailor the treatment to the patient, and thus have emerged as a method to reduce ADR, especially when they occur in drug metabolizing enzymes.

## ACKNOWLEDGEMENTS / REFERENCES

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### \*\*\*Works Cited:

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