Blueprint Diagnostics

MISSION: Double Cancer Survival Rates

World's Hottest Medical Trend? **Up to** 10X company revenues, You can help with only $300

Heligenics.com

www. blueprintdiagnostics.com

Watch the video pitch deck here

www.BlueprintDiagnostics.com/Brochure

What We* Can Dramatically Improve . . .

1. The Best Genetic Reports of Future Disease
2. Biomarker Discovery – have complete genes
3. Companion Diagnostics- First of its kind
4. Clinical Trials Efficacy increase 4-20%
5. Drug Rescue of Failed Drugs
6. Drug Development – Crystal Ball
7. Precision Meds – double recruitment and market share + new indications of use
8. Rare Disease DX and TX

*Heligenics.com and BlueprintDiagnostics.com

The Power

- We have more measured data on gene mutations and their functional effect on cells than everyone else on the planet combined with a 40 year head start.
- In 1 year, we will have double the data.
- Heligenics.com is the partnership company, Blueprintdiagnostics.com is the spin off company for disease prediction and companion diagnostics.

Dr. Martin Schiller's Story

- Taught his class of choice at UNLV
- 25 greatest scientific discoveries of last 500 years
- Better way to Measure is over half of those 25 discoveries

= GigaAssay – more accuracy and more quantity

Doing for last 20-50 years

- 30-50 years ago – did it in tissues
- Measuring ONE mutation as cell signal average
- One single experimental result per experiment

NOW Doing . . .

- GigaAssay = single molecule/cell measurement
- 100x + results for each cell
- GigaAssay = 10x, 100x, 1,000x other assays
- P values of 0.00000000000000000001%

FOR THE VERY FIRST TIME > WHOLE GENE BIOMARKERS

OUR UNIQUE ADVANTAGE – Why it's Virtually Impossible for our Technology to Get it Wrong…

GIGAASSAY TECHNOLOGY

WHOLE GENE BIOMARKER

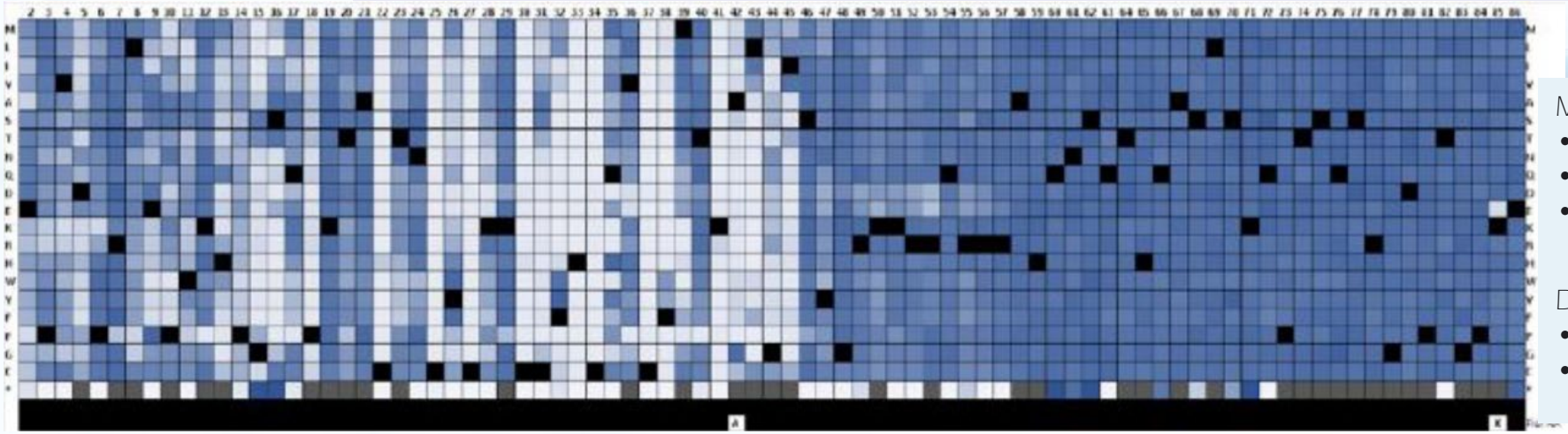
Problems We Help Solve

Why use 1 mutation when you can access all >100,000+ with a whole gene biomarker?

Unprecedented Accuracy and Scale

Accuracy: 94-100%
PPV: 100%

100,000s mutants at once in months
0.00000000000000000001% average
0.0 (ten to power 65) 1% on some



Many Applications

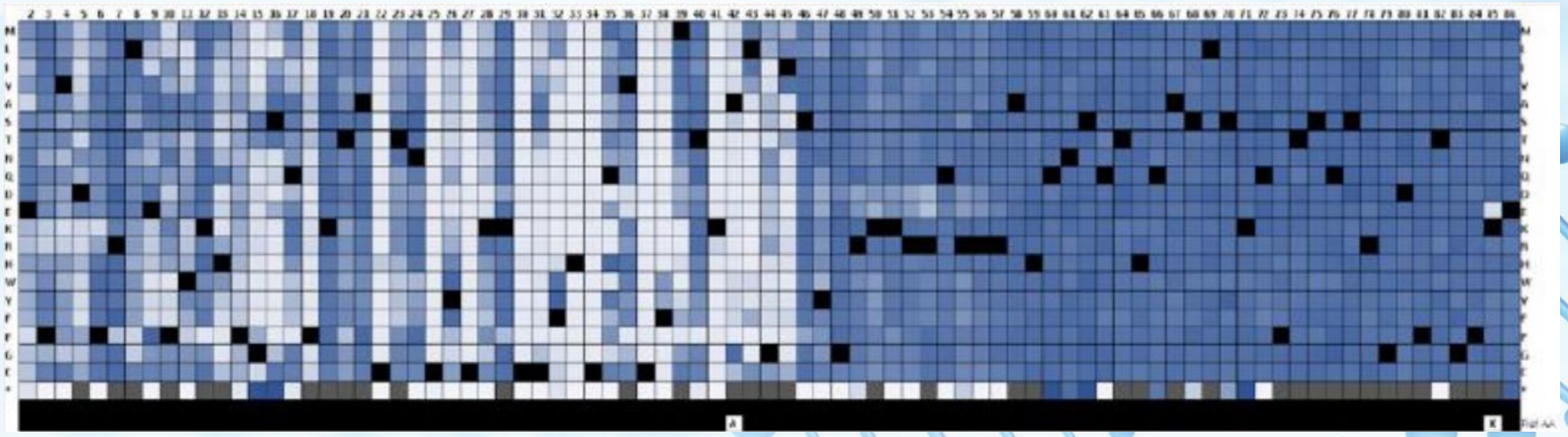
- Pharma
- Drug Dev and Rescue
- Clinical Trial Design
- Drug Resistance
- Patient Recruitment
- New Indications

Diagnostics

- Whole Gene
- Companion Diagnostics

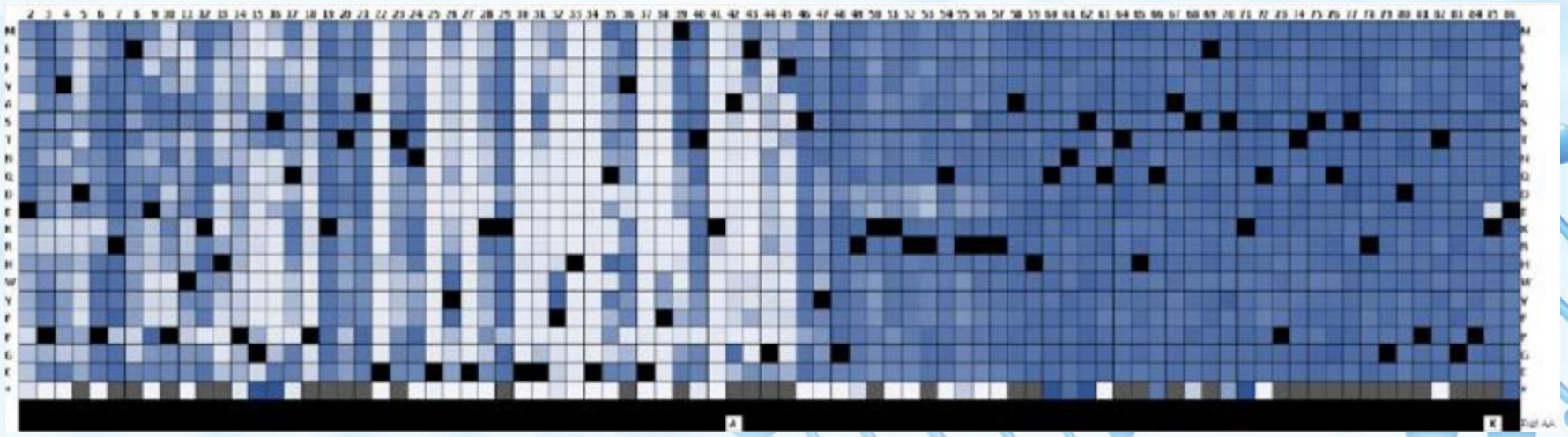
Rest of the world – 1% of this

Rest of the world combined only knows about 1% of the data for any gene on average. Some more, some less.



Normal Mutations

Only 6 mutations average out of 160,000 possible



Compare Mutations

Better Disease Prediction for the genes we have done than everyone else on the planet
We compare the two = If your mutations are on white – you are very likely to get the disease/dysfunction = If they are on blue – you are unlikely to get the problem

GIGAASSAY TECHNOLOGY

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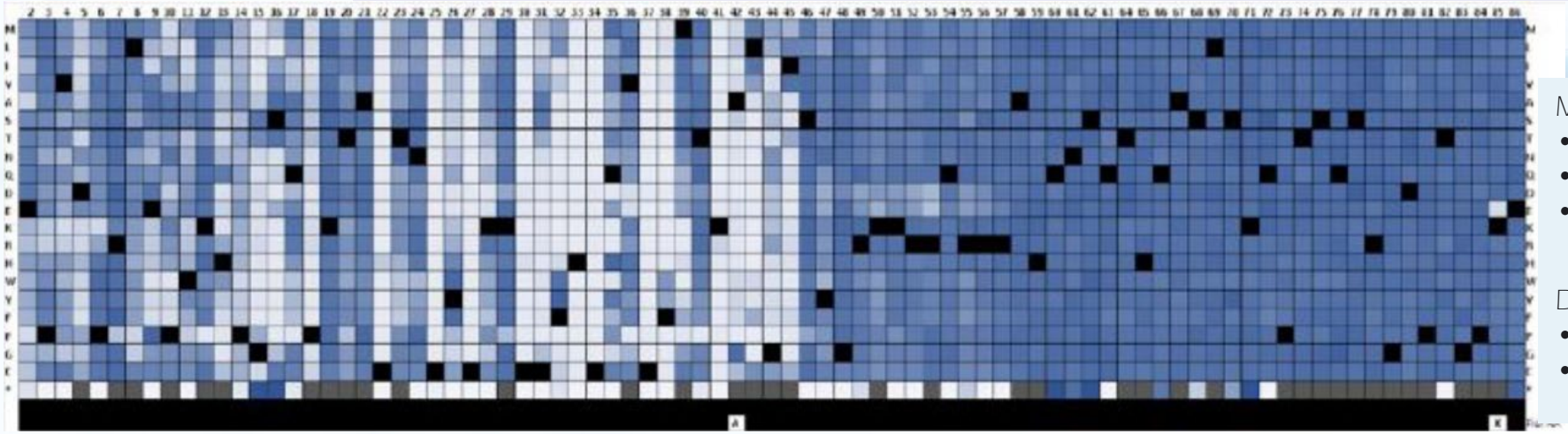

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Diagnostics

- Whole Gene
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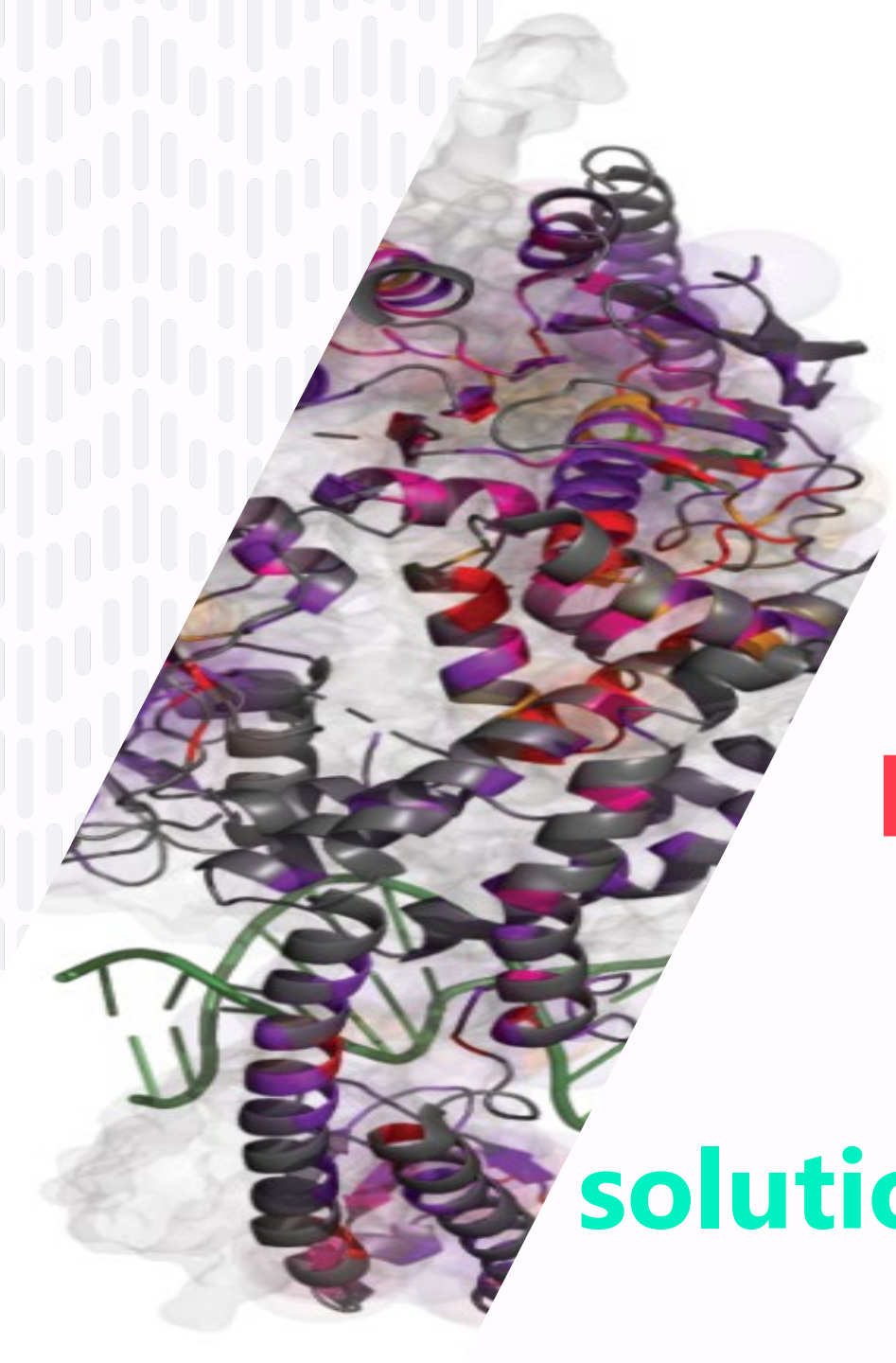


EXAMPLE OF

Lynch Syndrome *MSH2*

problem

- Diagnosis of Lynch Syndrome
- E483G and L173P are pathogenic missense variants
- 1,700 new loss of function pathogenic mutations (VUSs) with unknown function

solution

A *MSH2* full gene biomarker that uses all MSH2 loss of function variants for diagnosis and Tx

Experimental is New Gold Standard - ACMG

TIER I: VARIANTS OF STRONG CLINICAL SIGNIFICANCE

Therapeutic, prognostic & diagnostic

Level A Evidence

FDA-approved therapy included in professional guidelines

Level B Evidence

Well-powered studies with consensus from experts in the field

TIER II: VARIANTS OF POTENTIAL CLINICAL SIGNIFICANCE

Therapeutic, prognostic & diagnostic

Level C Evidence

FDA-approved thereapies for different tumor types or investigational therapies.

Multiple small published studies with some consensus

Level D Evidence

Preclinical trials or a few case reports without consensus

TIER III: VARIANTS OF UNKNOWN CLINICAL SIGNIFICANCE

Not observed at a significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases

No convincing published evidences of cancer association

TIER IV: BENIGN OR LIKELY BENIGN VARIANTS

Observed at significant allele frequency in the general or specific subpopulation databases

No existing published evidence of cancer association

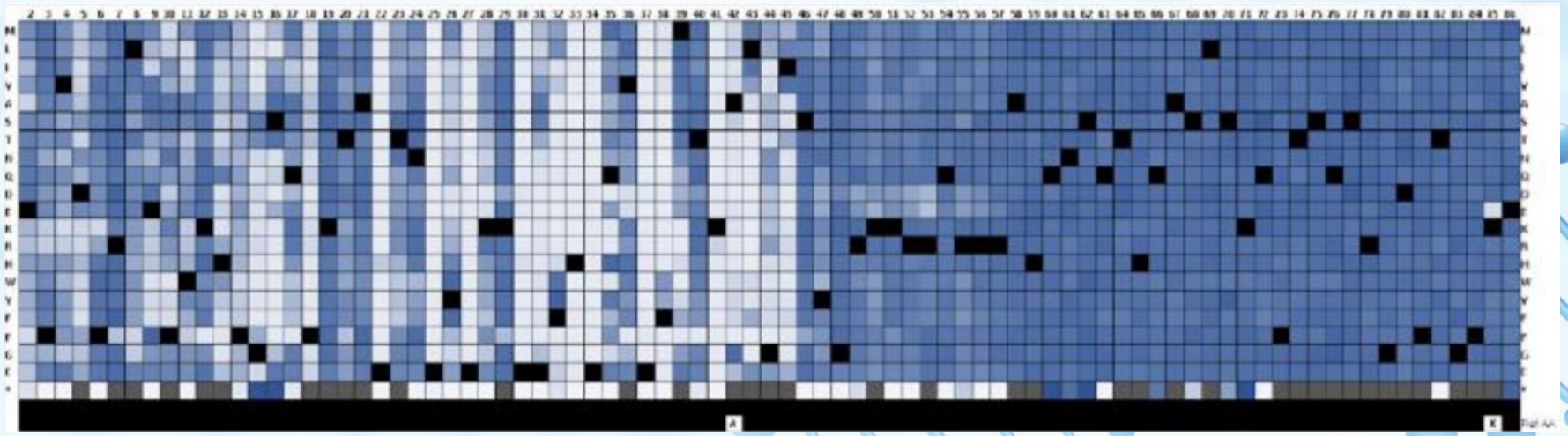
With Drug Present

First time in history – all resistant mutations are known

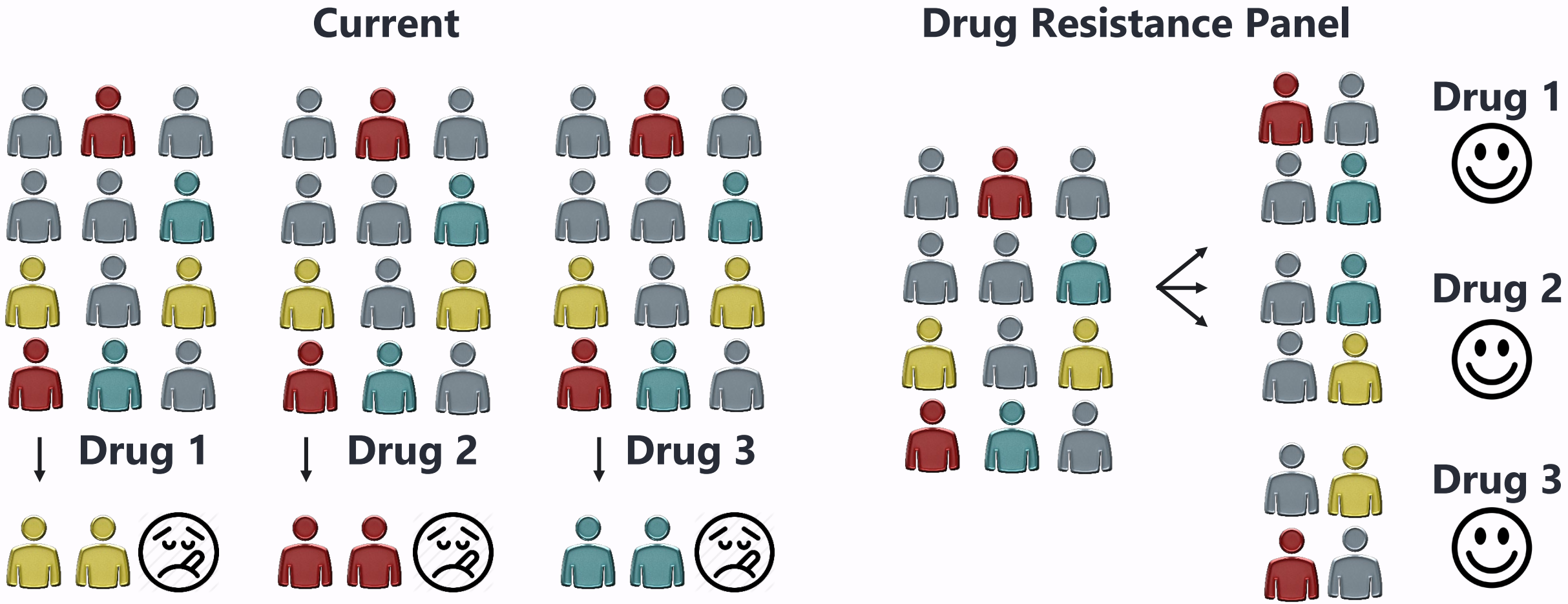
First time in history – high probability prediction of which drugs will wo

White stays white = 100% drug will not work for your mutation

White turns blue = probably drug will work



resistance panels for better Comp DX



one size does not fit all

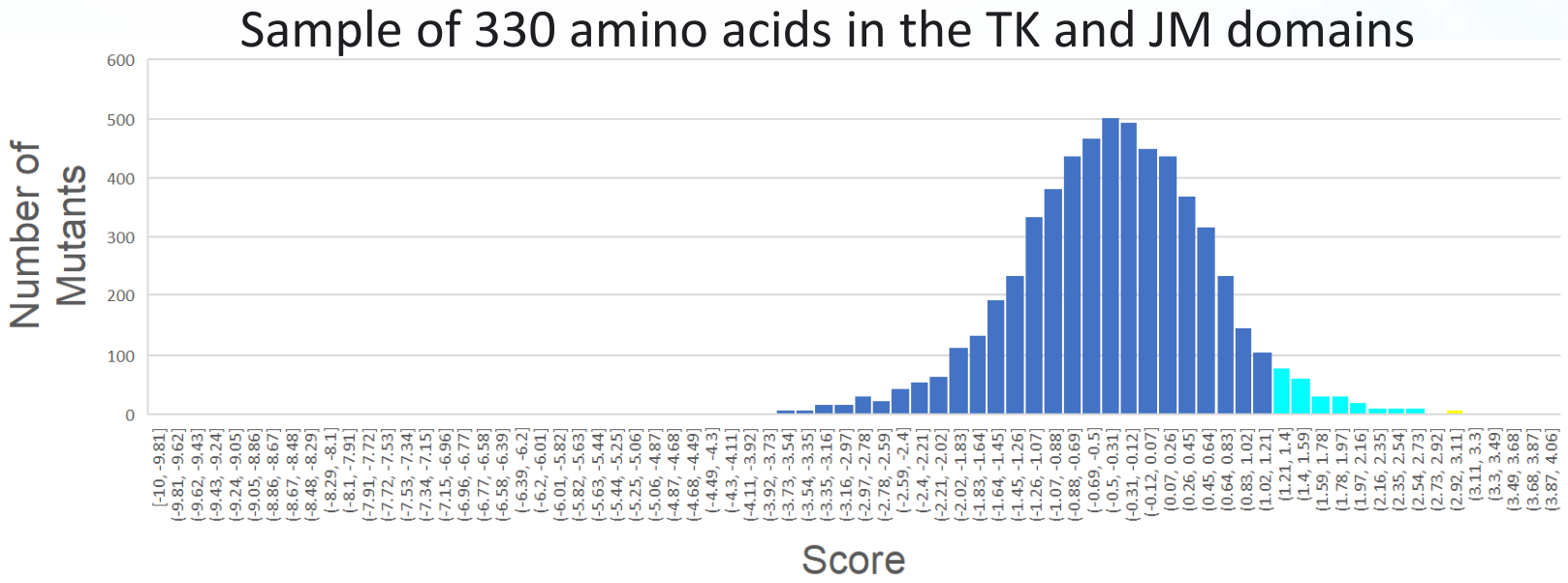
Percentage of the patient population for which a particular drug is NOT effective

Anti-Depressants (SSRI's)	38%
Asthma Drugs	40%
Diabetes Drugs	43%
Arthritis Drugs	50%
Alzheimer's Drugs	70%
Cancer Drugs	75%

From Spear and Huff et al. Trends Mol Med 2001 Clinical application of pharmacogenetics

Erbb2/HER2 Drug Resistance for BREAST CANCER

GigaAssay



Companion Diagnostic:
Lapatinib, Neratinib, Tucatinib

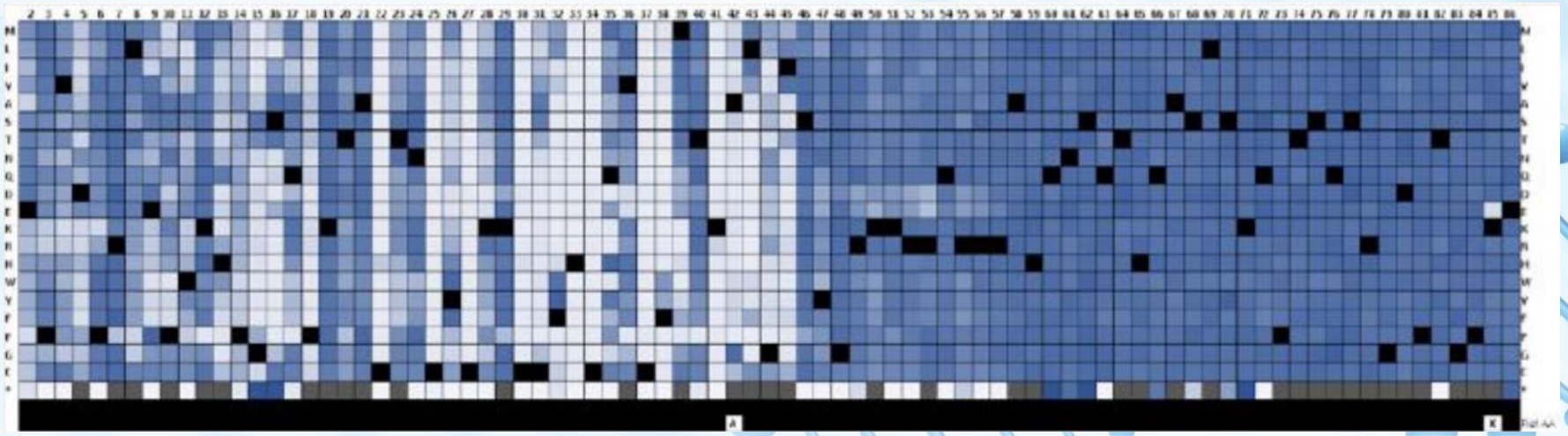
L755P, L755S, V842I
known RESISTANCE MUTATIONS

247 MORE WE FOUND

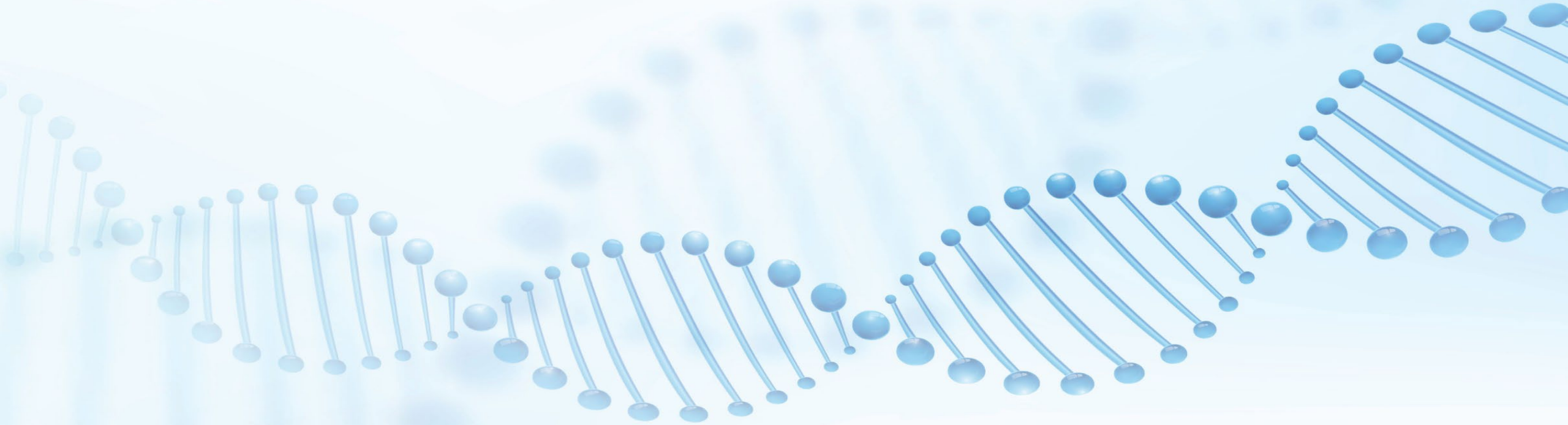
Cyan

HER2 and EGFR almost Done

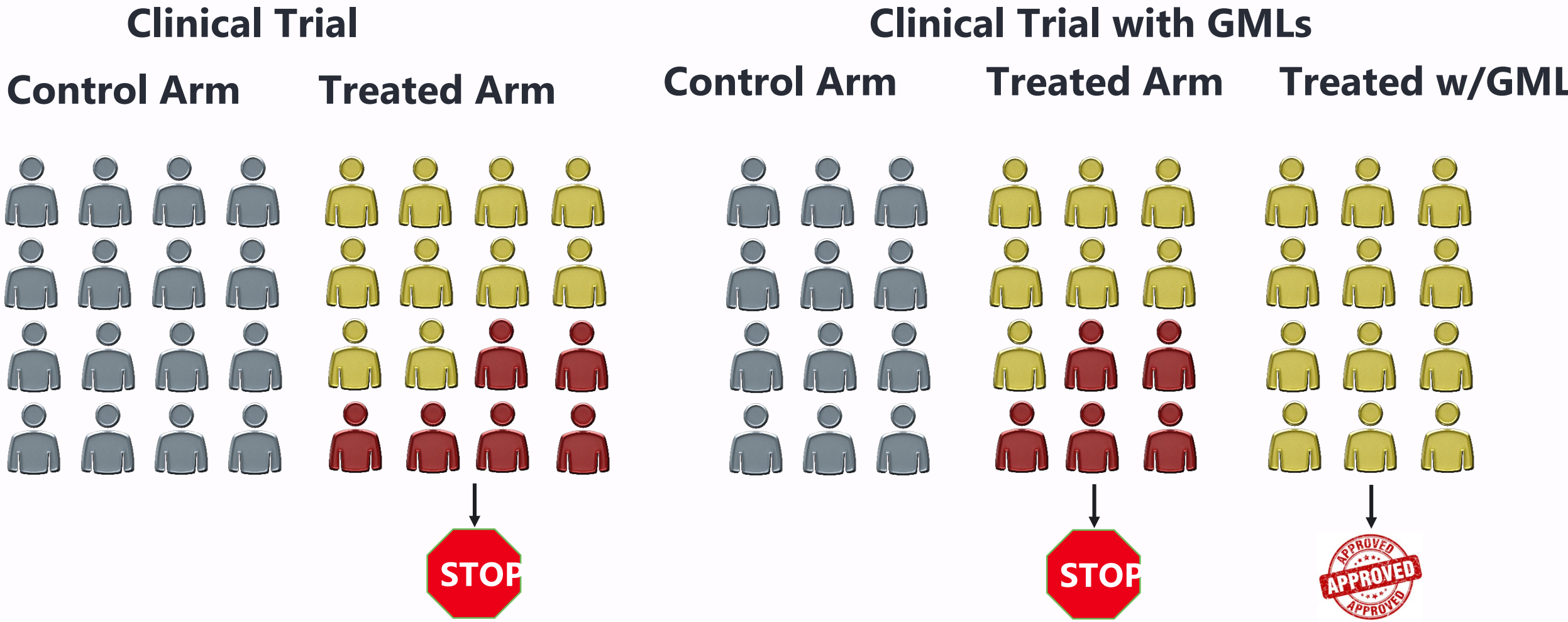
- Lapatinib, Neratinib, Tucatinib for HER2 Complete and ready to be used by all HER2+ Cancer Patients
- 11 EGFR drugs coming within the year

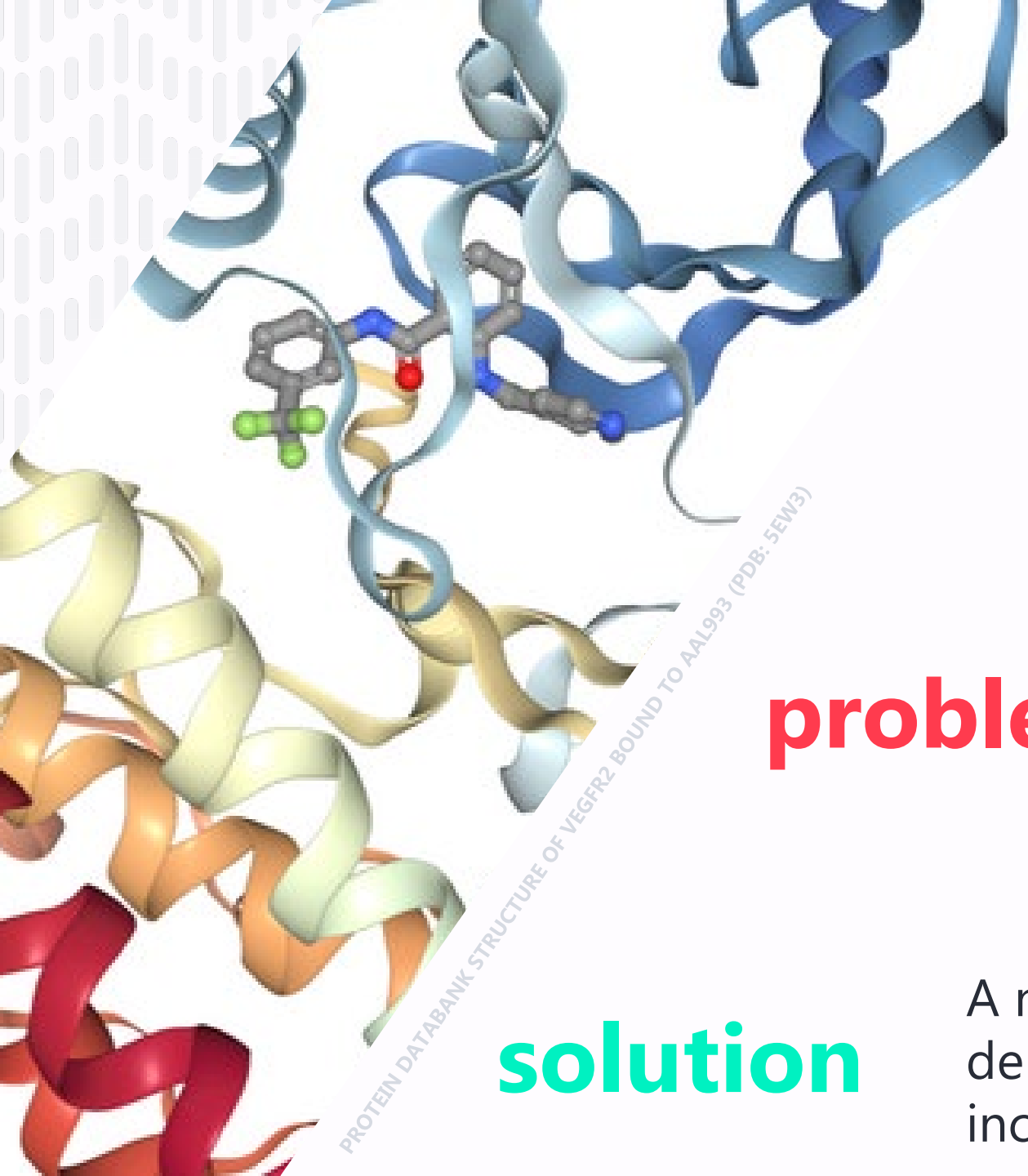


Heligenics.com for the following slides and products



4 – 20% increased trial efficacy





EXAMPLE OF

brivanib

problem

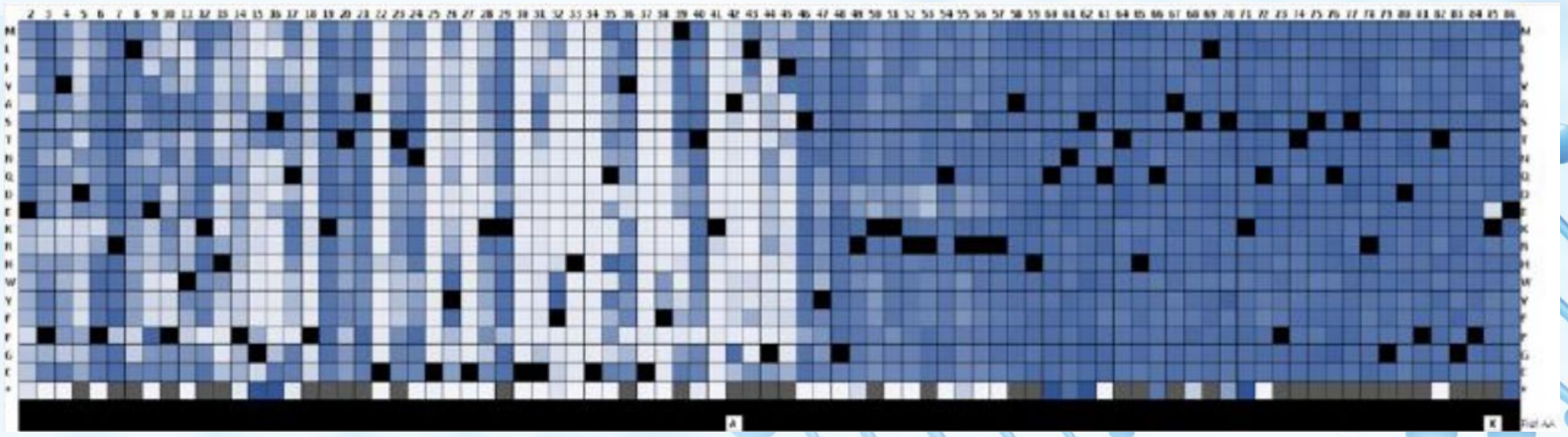
- Treatment for Hepatocellular Carcinoma
- 25 clinical trials failed
- 20 amino acid substitutions in the binding site affecting safety, efficacy
- Likely 100’s more

solution

A new trial that excludes participants with deleterious SNPs (mutations) will greatly increase chances of success

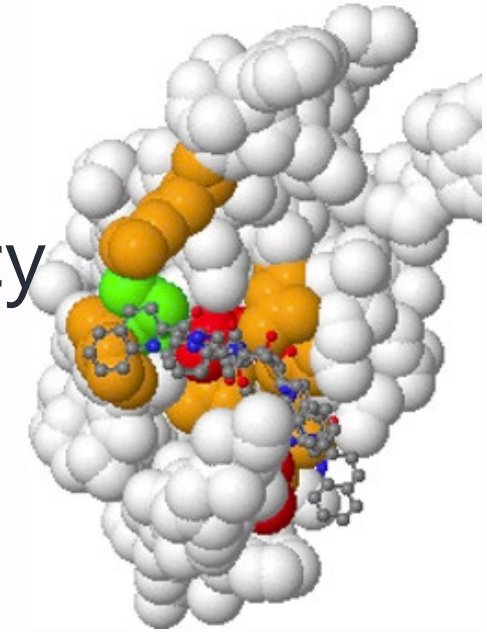
With dozens drugs/compounds Present

- We can do this for relative trial efficacy, not just affinity



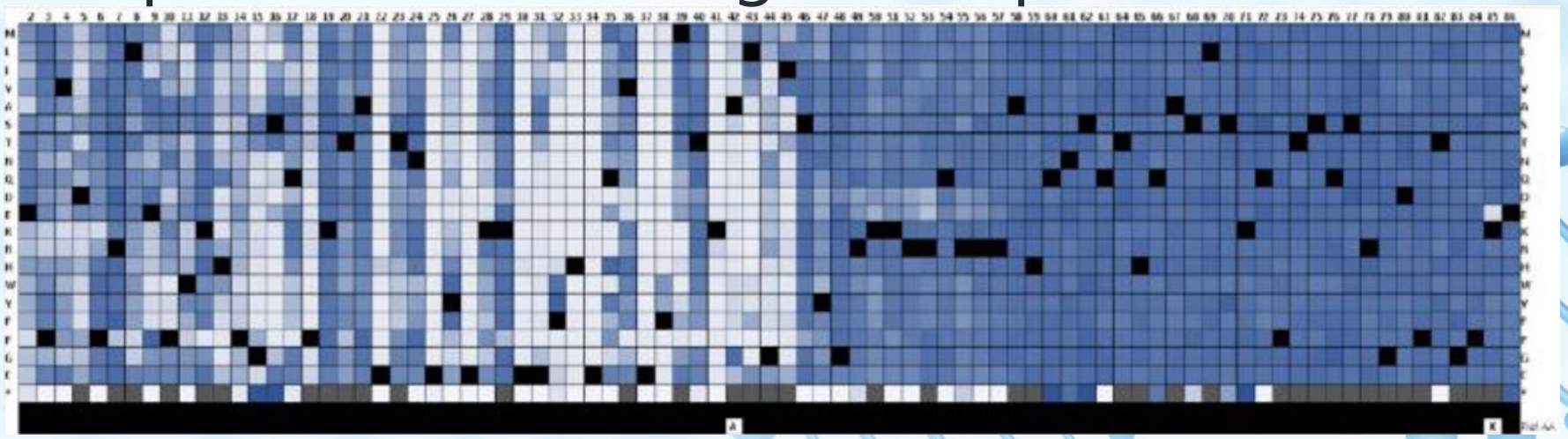
Crystal Ball to Predict Relative Trial Efficacy during Drug Development

- First time in history - See real world results in each cell for relative efficacy in future clinical trials (NOT Artificial intelligence)
- Mutations in Drug binding sites affect efficacy
  - Source of resistance
  - Beneficial mutations
  - Common variants
- Helps in clinical trial design



Peptide/hormone is Like a Gene

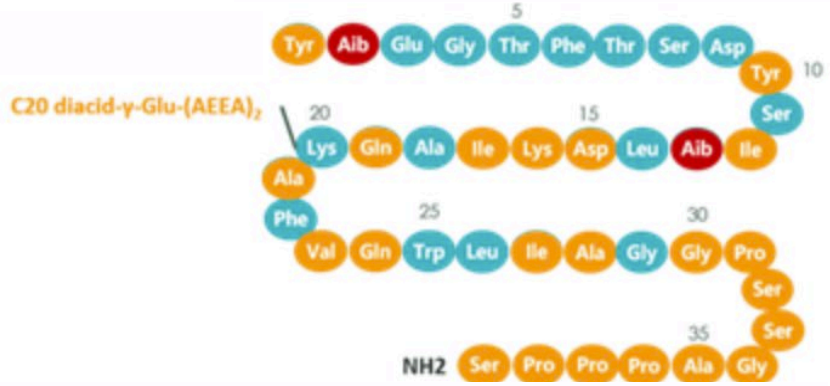
- In the US – biosimilar – in Europe – biologic
- We can mutate 20,000 and find similar that works
- Can do “generics” before patent runs out if it is protein based drug - Also patentable



Peptide/Hormone DRUG DISCOVERY

Problem	Existing tech. challenge	GigaAssay solution
Rapid screening of peptide space for new biologics or biosimilars	Phage display, yeast display, MAVE screens assess have high false positive rates and do not measure target function	GigaAssay is accurate and can easily assess 10,000s of single, double, and triple mutants for target function in a native context

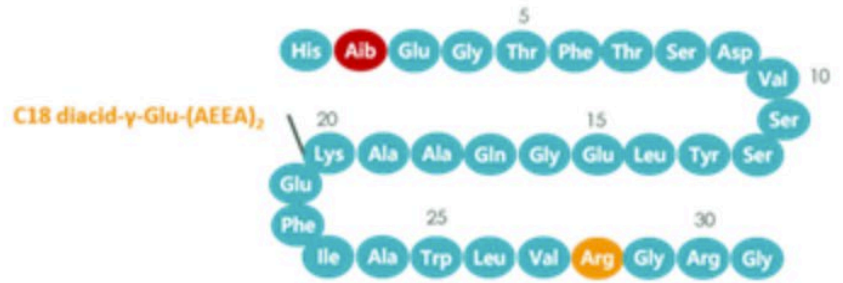
GigaAssay – create mutations like gene



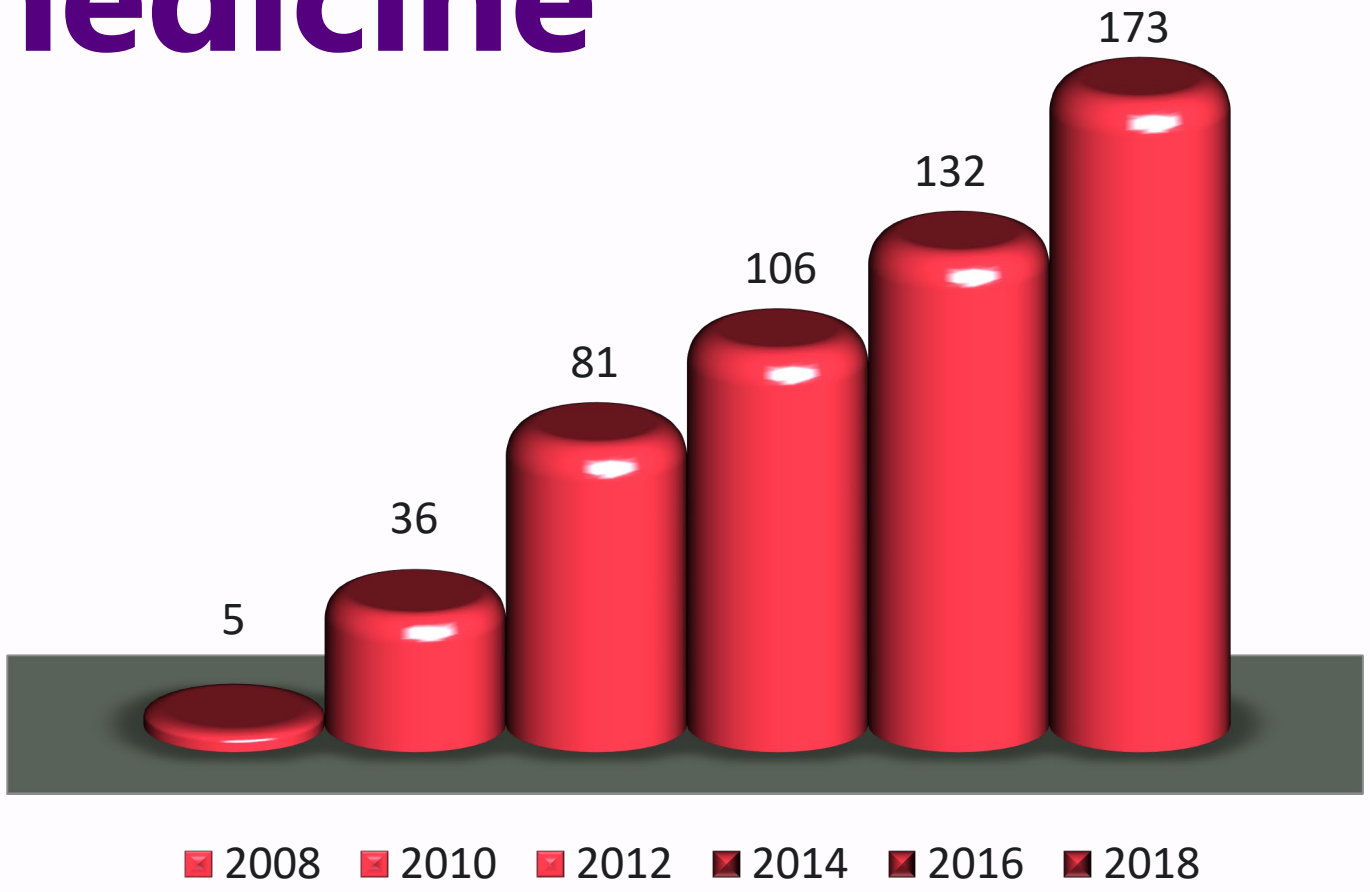
Screen 10-20,000 variant sequences at once for efficacy (not just binding)

Identifies Biosimilars/Biobetters/biologics:
100s of new sequences with similar activity -Dozens of new sequences with better activity
Patentable – vary 2 in the sequence

Measure Efficacy in cells



emergence of precision medicine

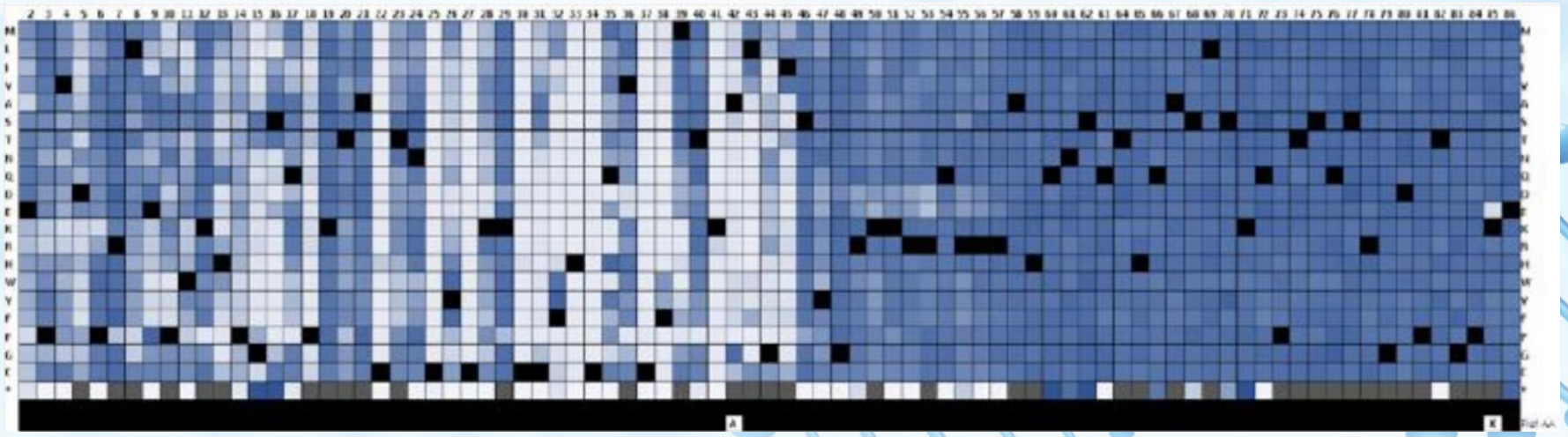


- 46% of total recent approvals
- One or few genetic markers

From "The Personalized Medicine Report: 2017 Opportunity, Challenges and the Future". http://www.personalizedmedicinecoalition.org

Most only use 1-3 mutations We identify 100-300 per gene

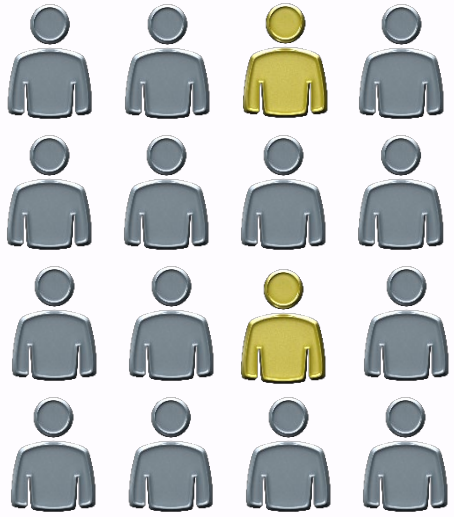
- They will respond identically to original 1-3 mutations identified



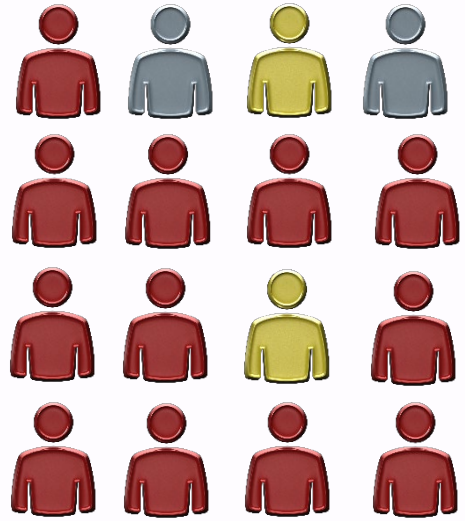
Precision Med Biomarkers (100-300)

- Instead of 1-3 – we give you 100-300 which will Double recruitment speed and Double market share

Single Mutation Biomarker



GML Gene Panel Biomarker

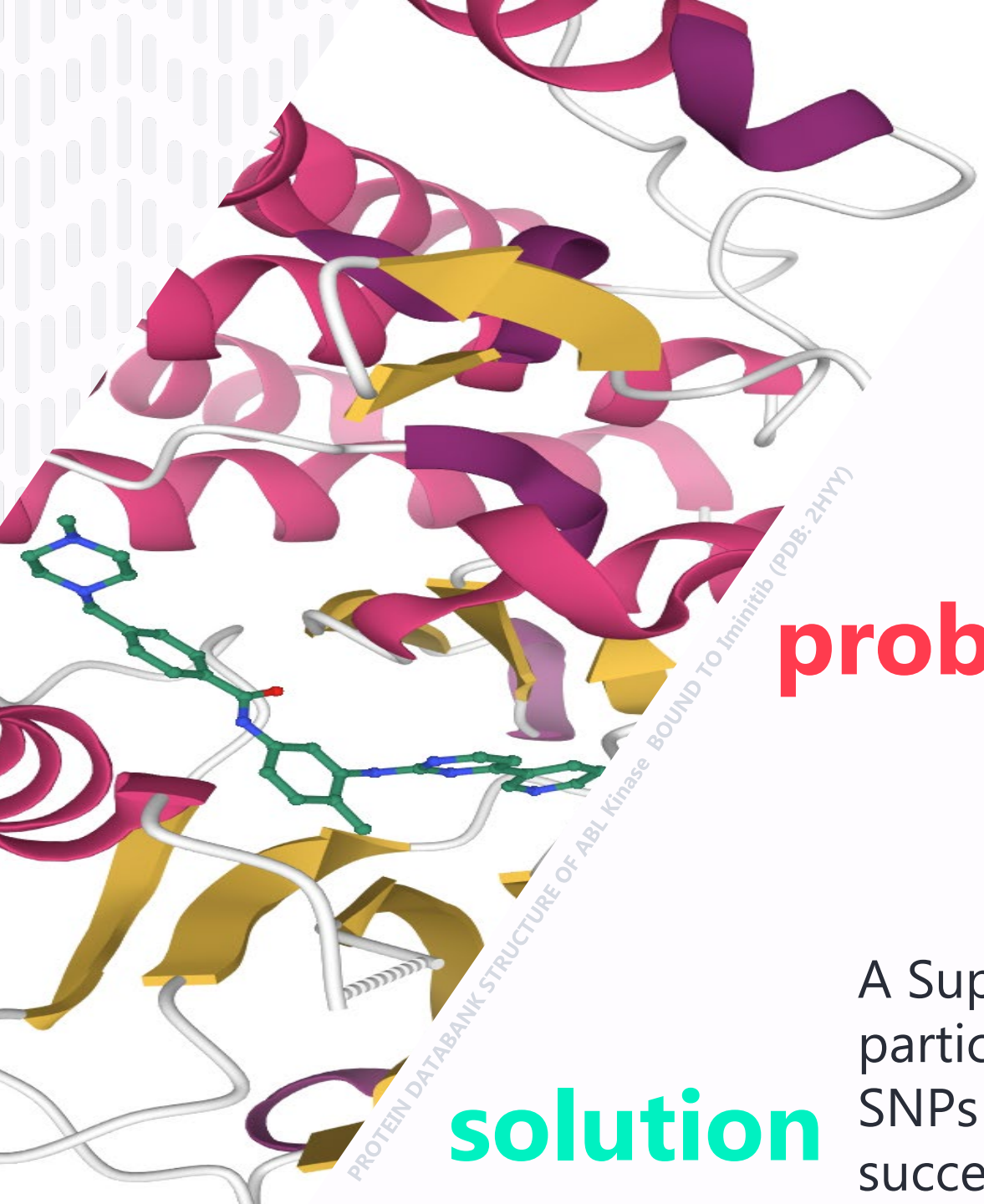


Disease, but lack Single Mutation Biomarker

Disease with Single Mutation Biomarker

Disease with Gene Panel Biomarker

Better Diagnostic Yield



EXAMPLE OF

Iminitib

problem

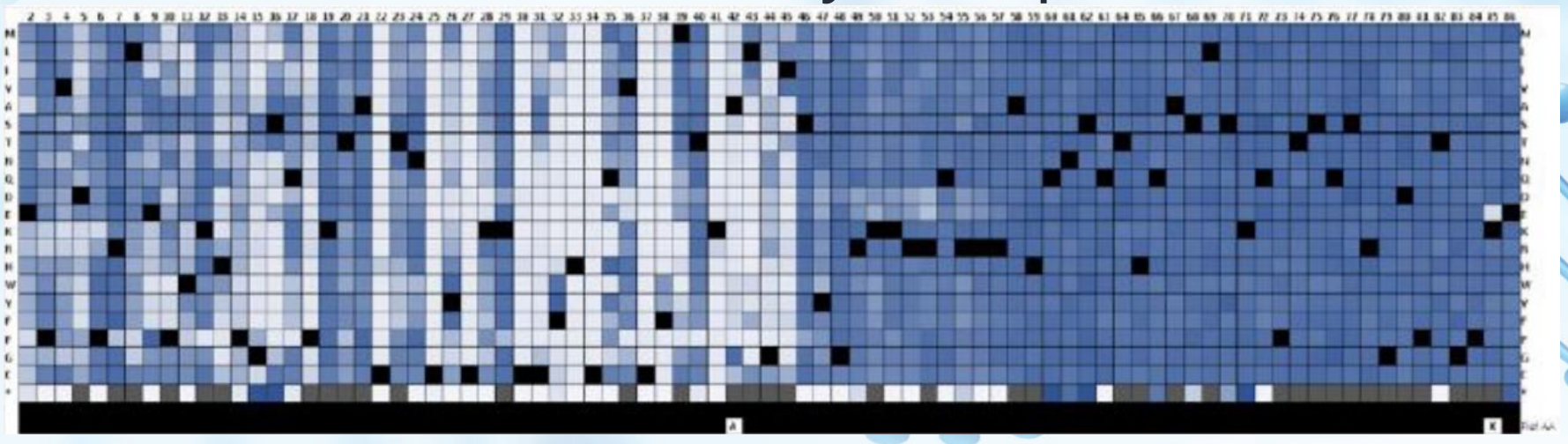
- Treatment for Acute Lymphoblastic Leukemia
- 1897 observed amino acid substitutions in ABL affecting safety and efficacy – but unkown how
- Almost all VUSs

solution

A Superprecision clinical trial that excludes participants with a complete panel of deleterious ABL SNPs (mutations) will greatly increase chances of trial success (estimated 4-20% increased efficacy)

50% rare disease is unique mutations/biomarkers

- We can map out any gene and test dozens of compounds to treat it in 9-12 months
- Know relative efficacy of top candidates in trials



Failed Drugs 4–20% + efficacy

Normal Clinical Trial

Control Arm

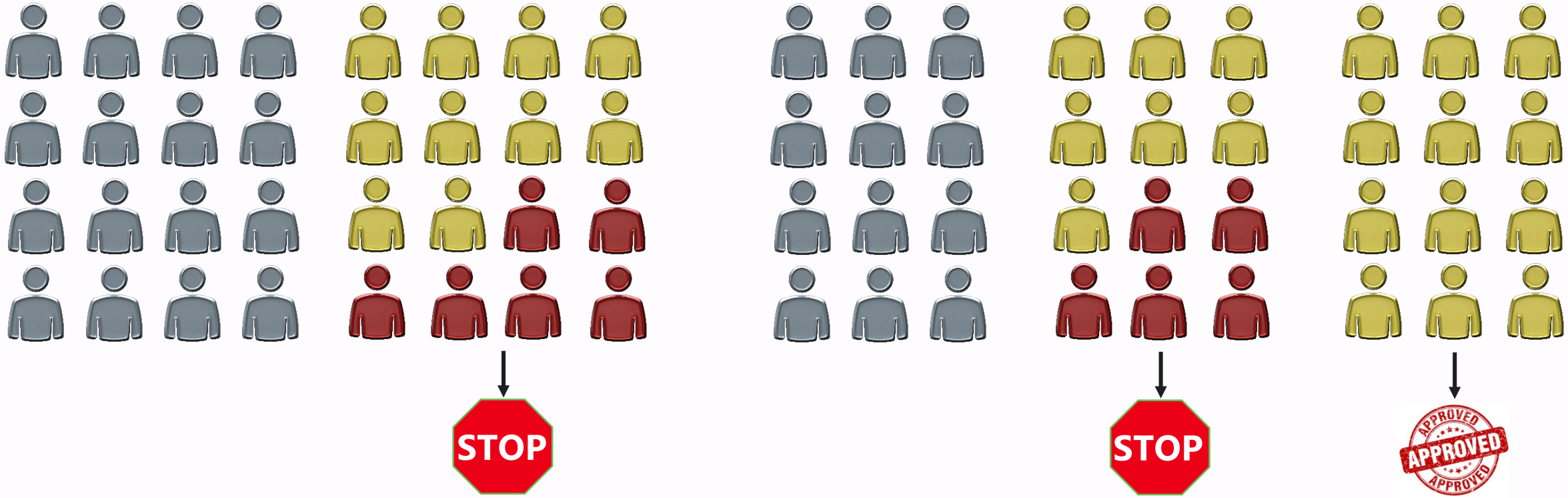
Treated Arm

One New Clinical Trial for Approval

Control Arm

Treated Arm

Treated w/GML



placebo

treated responder

treated non-responder

treated excluding genetic biomarkers for poor safety or low efficacy

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*Heligenics.com and BlueprintDiagnostics.com

Ideal Partnership Blueprint

1. $1.5M order for tests or data
2. $1.5M investment
3. Out License either per Use Tests or Data to do as many tests as you want (country or regions)
4. Company to promote/sell tests to patients in hospitals and license to doctors for their patients
5. Person to help get insurance payers to pay for the test
6. Partner with a trial for one of the genes/drugs we already have done for more real world proof

Ideal Partnership Heligenics

1. Partnering to help bring 5-10 new biosimilars/biologic drug candidates to market and sell them over next few years. FDA requires only phase 1 trial – then IND
2. $5m to $10M deposit on first Biosimilar/biologic candidate to secure the rights (available end of summer)
3. Out licensing the FDA IND ready candidate (18 months)
4. Out Licensing the candidate in other countries and regions

CONTACT US

BlueprintDiagnostics.com/fundify – to invest

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Partnering Company – www.Heligenics.com

For Scientists

A publication preprint under consideration at Nature Methods https://www.researchsquare.com/article/rs-708936/v1 demonstrates the power of this innovative novel approach that all drug companies will be using in 5-10 years

Bonus

Future

- Identifying Off-Target Drug Interactions
- Minimize side effects, cell toxicity, and cross-reactivity
- Multi Drug Interactions experimentally