Help Us Solve
The Cruel Mystery

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Welcome!
Lupus Research Action Network Day 1

October 26, 2021

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Welcome and Opening Remarks

Steve Gibson

President and CEO

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Overview

Pat Wildman

Vice President, Advocacy and
Government Relations

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Goals and Objectives

- Increase Understanding and Importance of Lupus Research
  - What is research?
  - Awareness and education
  - Advocacy
- Increase Participation in Lupus Research
  - Opportunities
    - What you can do, how you can do it
- Help Solve the Cruel Mystery!

The Next Two Days…

- Today
  - Clinical Trials 101 and Drug Development
- Tomorrow
  - The Power of the Patient Voice
- Conversation - Ask questions, share your experience, excitement, concerns, ideas
  - Utilize chat feature or speak up!

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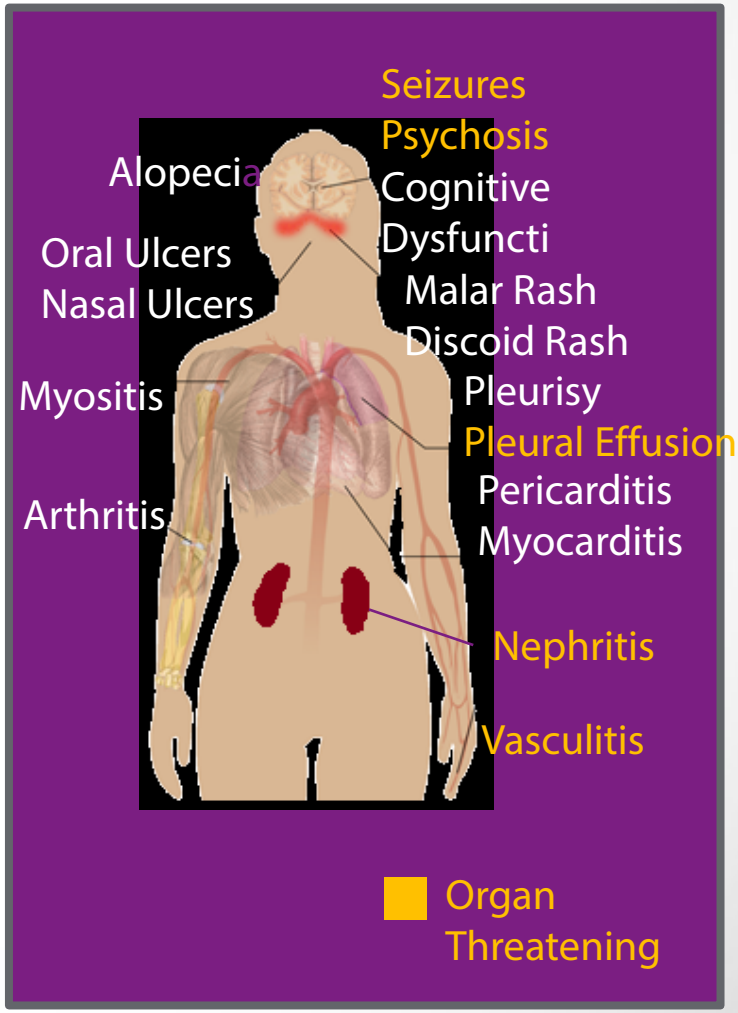
Lupus Research Action Network Part 1: Why Are Clinical Trials So Important For Lupus Patients?

What is Lupus?

- Imbalance of immune system
- Mild, moderate, or severe inflammation in one or more parts of the body
- Can last for decades or a lifetime
- Can come and go with sudden flares
- Most common in women of childbearing age, but can occur in men, women and children of all ages



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What is the impact of lupus on family, employment, and quality of life?

- There was limited information about this
- So the Lupus Foundation of America did a survey

M Crimmings,[1] K Lerstrøm,[2] M Govoni,[3] D Isenberg,[4] JT Merrill[5]

[1]Lupus Foundation of America, Washington DC, USA; [2]LUPUS EUROPE, Romford, UK; [3]UCB, Brussels, Belgium; [4]University College London Hospitals, London, UK; [5]Oklahoma Medical Research Foundation, USA

Presented at the World Lupus Congress Vancouver B.C. 2010

Who Filled Out the Survey?

- 531 people with lupus (each question was answered by at least 500 of these people)
- Most (93%) were women
- 86% were between 20–50 years old
- 36% were married, 28% were single
- 31% were parents with children

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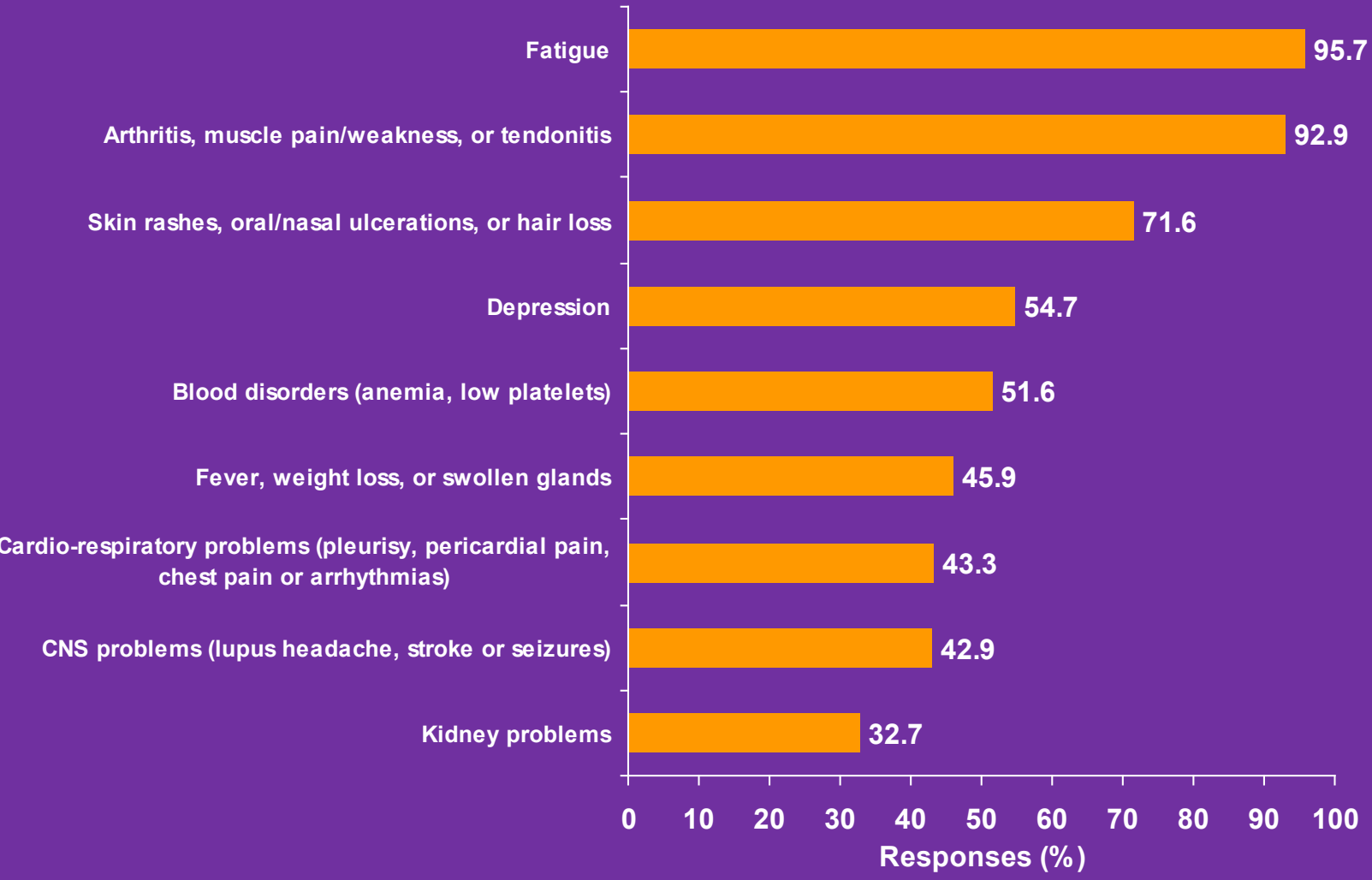
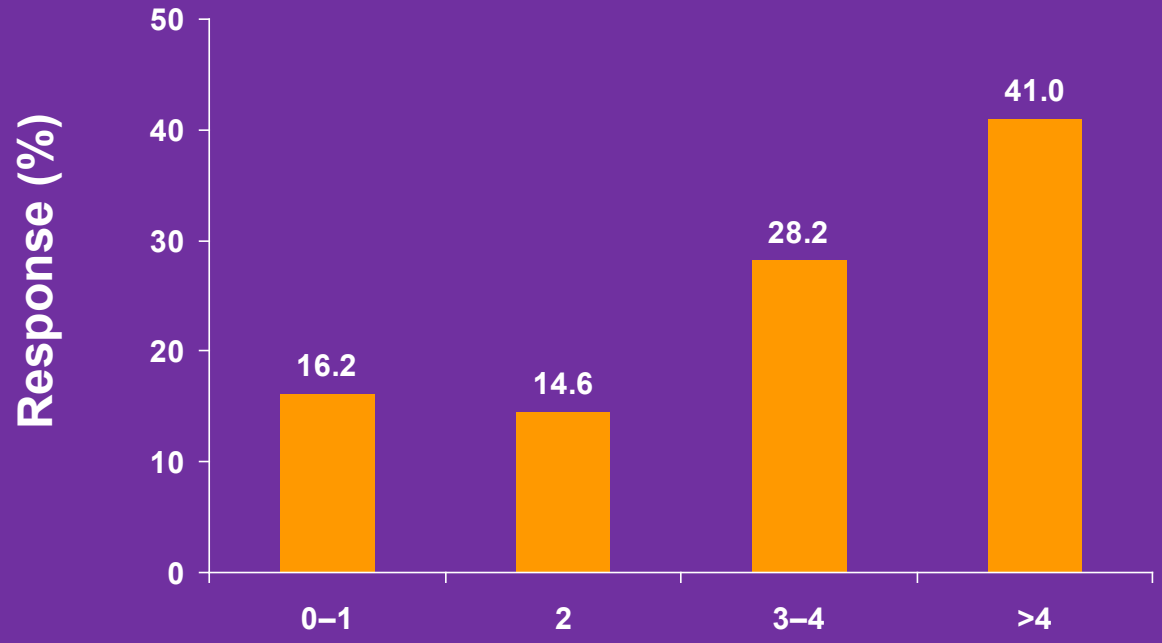
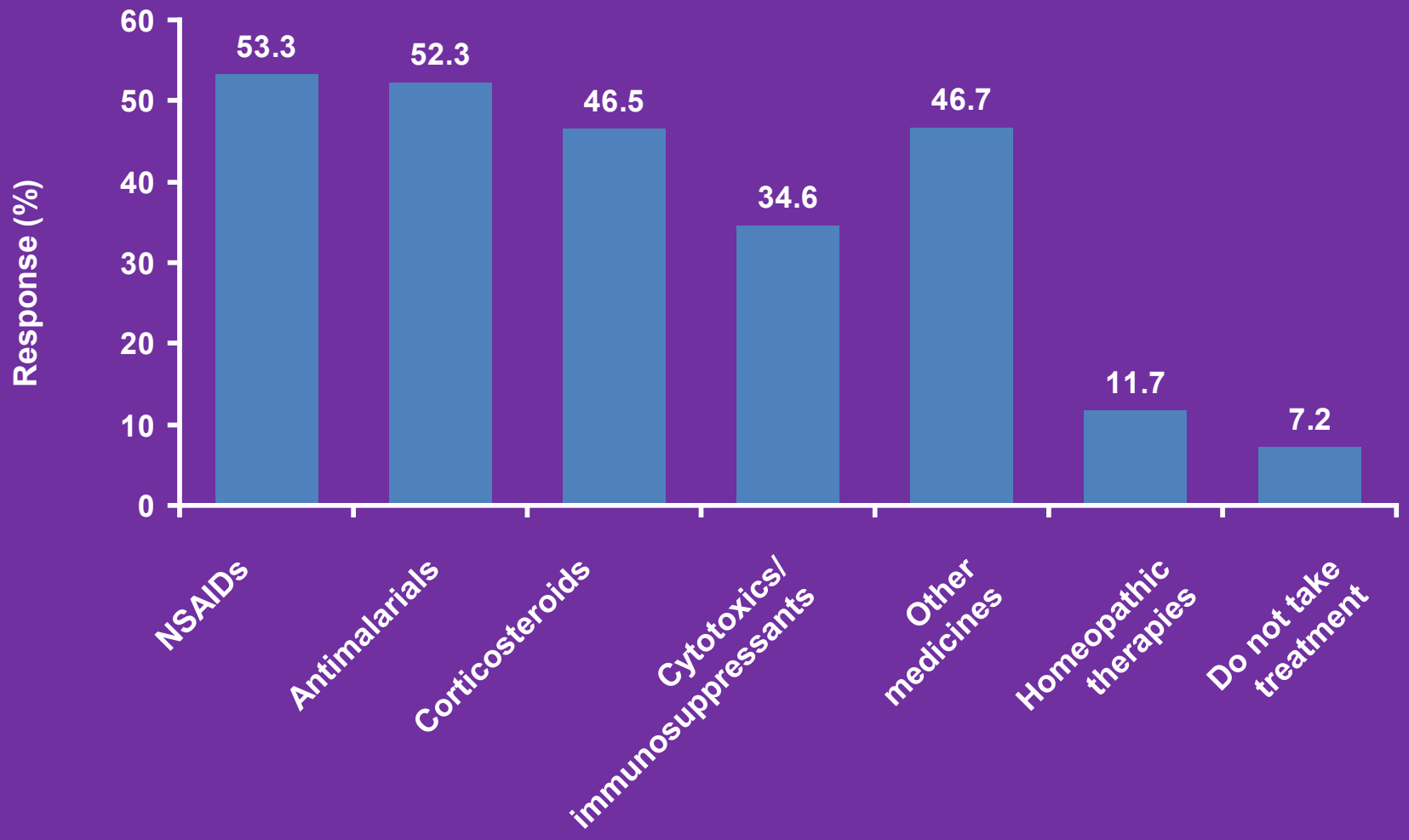
Most common symptoms of lupus experienced by patients



Number of lupus flares per year



Treatments for lupus



How do people with lupus feel about their current treatment?

‘satisfied’ or ‘very satisfied’ 44%

Neutral 42%

Very dissatisfied 15%

Medications impair daily activities or work? 45%

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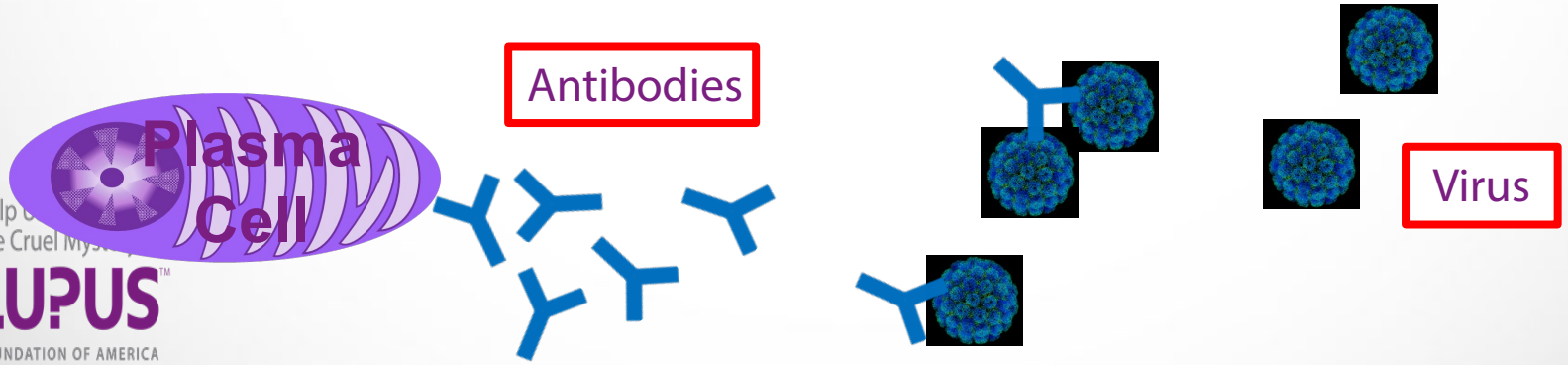
What Should You Explain to Patients About the Cause of Lupus?

- Many patients have been told that lupus is a condition where their own body is attacking them.
- That is not exactly right. Thankfully!
- If a person has lupus it is because their body is trying to defend them, but the response in the immune system has become disorganized.
- How does that happen?

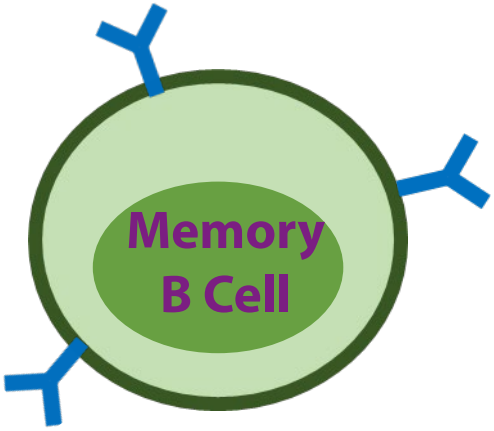
Normal Immune Function

- To control our response to invaders into our body, some parts of the immune system trigger inflammation and other parts calm it down.
- When a virus, bacteria, fungus or toxin gets in the body, we are very good at identifying the threat and setting off an army of little proteins (including specialized proteins called antibodies) that can recognize and attack the invader.
- How the parts of the immune system interact with each other is very complicated and extremely well orchestrated.



Immunologic Memory

- Once the threat dies down, we are also good at slowing down the inflammation, but we keep a “memory” of that invading object
- The next time it tries to get in our body we will be better prepared and may be able to eliminate it more efficiently and with less inflammation



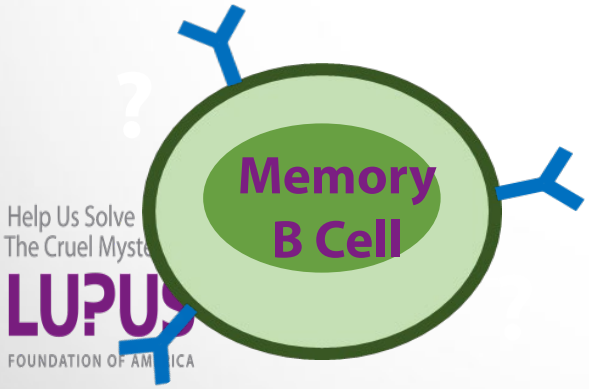
The Tricks Pathogens Play

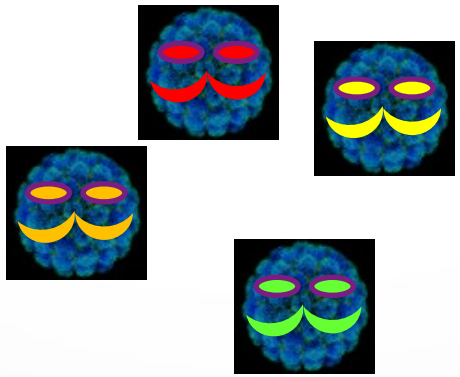
And Our Versatile Immune Response

- Viruses and bacteria can mutate so that our immune memory may not recognize them anymore, so just as we have clever ways to stop invaders from the environment, they have strategies to get back at us as well.

- If we all had the same exact immune system eventually some invader would learn to avoid that single immune system and wipe out the human race

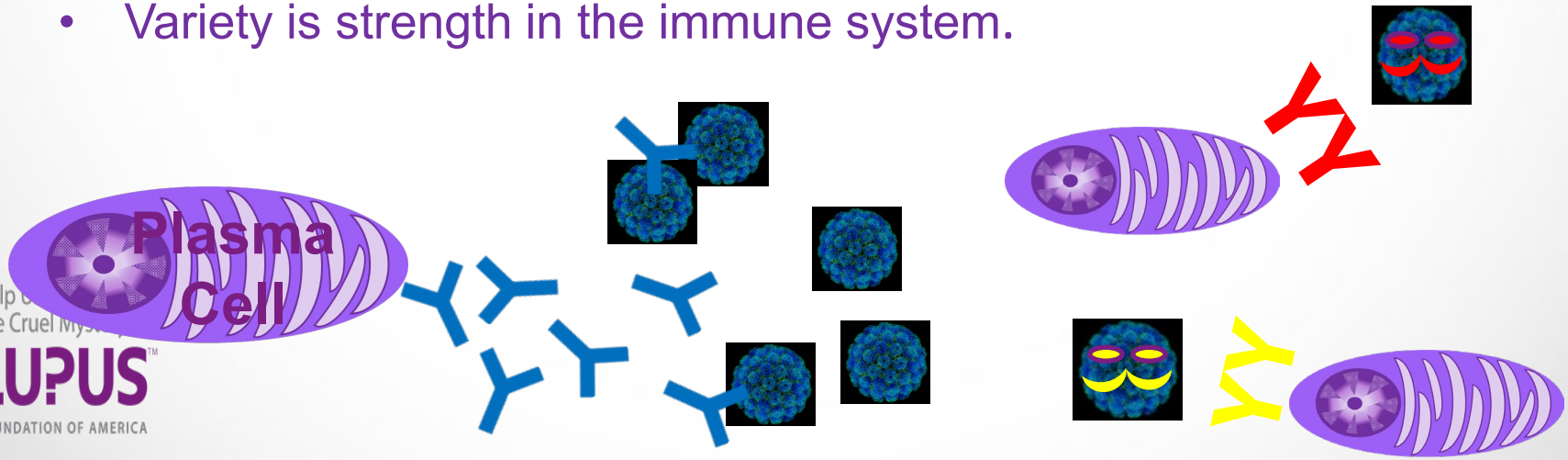
- Fortunately we are versatile





Diversity & Immune System

- Since we inherit our DNA from both parents, every individual ends up with a unique series of interacting proteins and cells that make up the immune system.
- So every person has a unique strategy (different from others) to protect them from the invading environment.
- Actually most of us have a **large** repertoire of strategies
- Variety is strength in the immune system.



Diversity & Lupus

- Because we inherit random combinations of proteins that make up the immune system, some people have stronger immune systems than others….
- ….and some people are so responsive to certain triggers that they are bound to get lupus
- Lupus occurs when something sets off an immune response that reacts strongly and can't seem to stop itself.
- A relentless perpetual motion machine is set off that keeps going around and around, even when the original threat may be long gone.

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Race/Ethnicity & Lupus

- Genetic variations are scattered throughout the whole population but specific gene variants will be more common in some races than others. It makes sense that lupus is more common in people of some races than others.
- Lupus is more frequent in African Americans, Hispanic/Latinos* and Native American groups
- SLE is more active in Hispanic and African American patients compared to Caucasians (1)
- Prevalence and incidence of SLE in Native Americans was found to be 178 per 100,000 person years and 7.4 per 100,000 person years and is similar to the US African American population (2)

1. Alarcon et. al. Lupus 1999 (8).
2. Furucci et al. A&R 2014 66 (9).

*Hispanic/Latino people are not one race, but this ethnic group is enriched for mixed races

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Types of Research

Subject	Types	Methods	Risk	Benefits
Test Tube			Minimal	Proof of Concept
Animal	Safety	Toxicity Studies	High	Dry Run
	Efficacy	Disease Models	High	Dry Run
Human	Observational	Retrospective	Minimal to Moderate	Testing of Disease Model for Relevance
		Cross Sectional		
		Prospective		
		Cohort		
		Case Control		
	Interventional	Clinical Trial:	Moderate to High	Potential Direct Benefits: Must outweigh Risks
		Open Lable		
		Placebo controlled + blinding		
		Randomized		

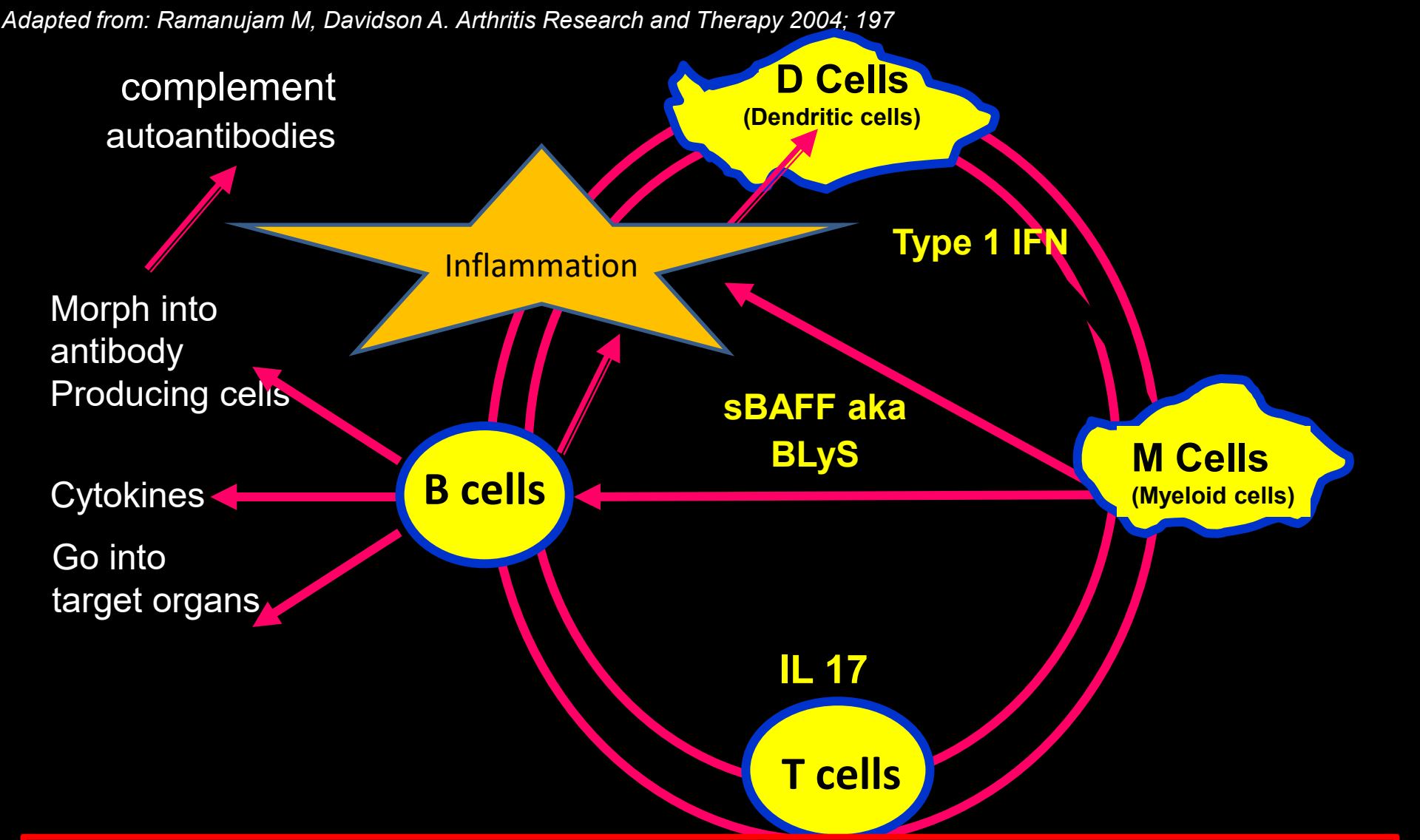
Stages of Research

Stage	Type	Safety	Efficacy
Preclinial	Test Tube Animal Human observational or blood donation	X	X
Clinical			
	Phase 1 SAD	X	
	Phase 1 MAD	X	
	Phase 2	X	X
	Phase 3	X	X
	Phase 4 (post-marketing)	X	X

Participation in Clinical Trials

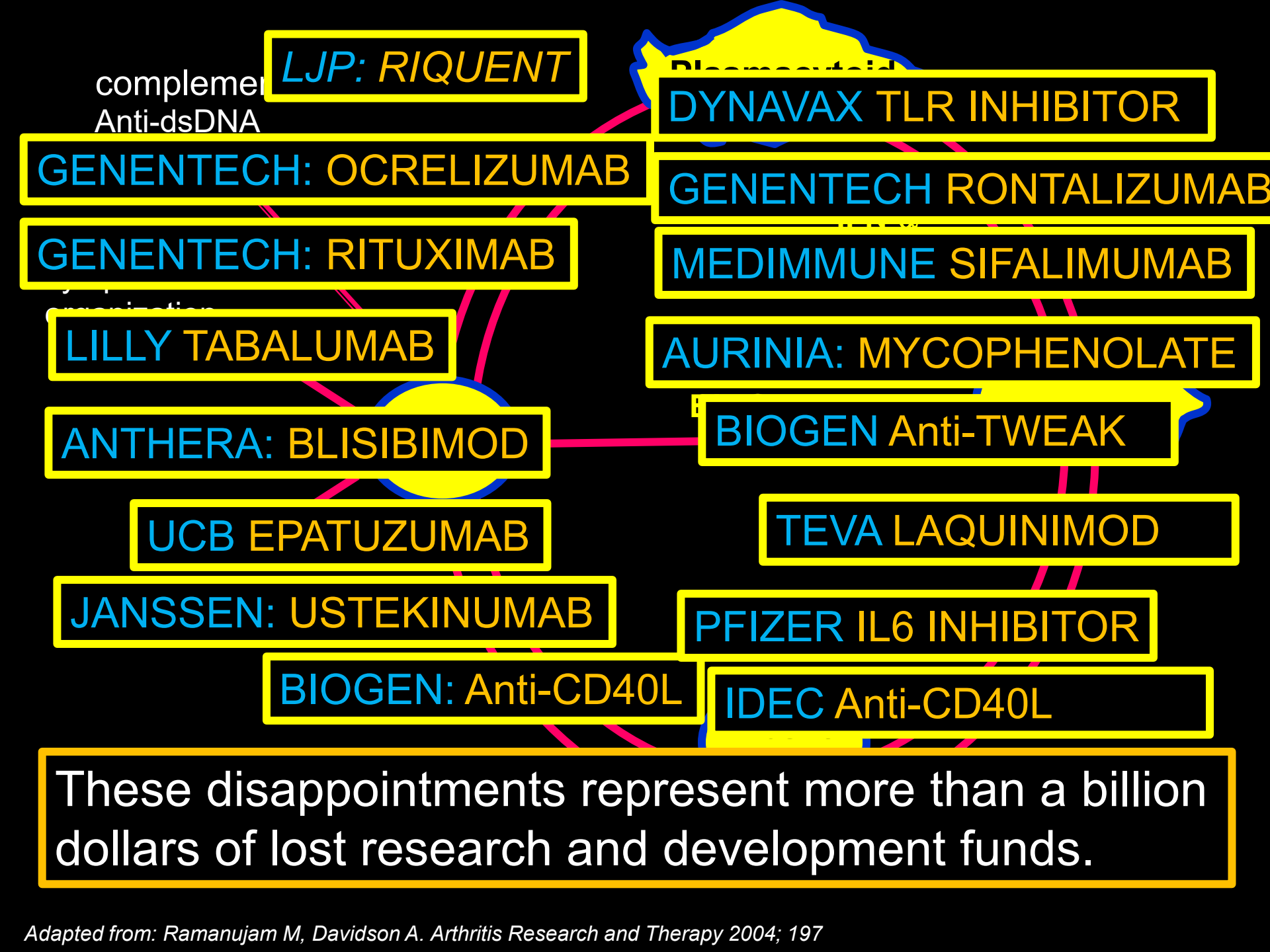
Benefits	Risks	Remediations
Treatment may help	Treatment might hurt	Informed Consent Close monitoring Access to Care Coverage of Expenses
Privacy (Names withheld)	Loss of Privacy	HIPPA Protections Violation Reporting
Access to Extra Care and State of the Art Monitoring	Costs/ Lack of communication with usual medical team	Rights to records No charge for study tests

Adapted from: Ramanujam M, Davidson A. Arthritis Research and Therapy 2004; 197



This is a cartoon of the immune system showing how the different immune cells interact with each other. When the immune system senses a threat from the environment, it starts the wheel turning. Because of the circular way in which it operates, this could turn into a perpetual motion machine if there is nothing to stop it. Fortunately most of us are equipped with ways to slow down the process once the threat is gone.

Given How Complicated and Diverse the Causes of Lupus Are We Have Been Delayed in Finding Better Treatments

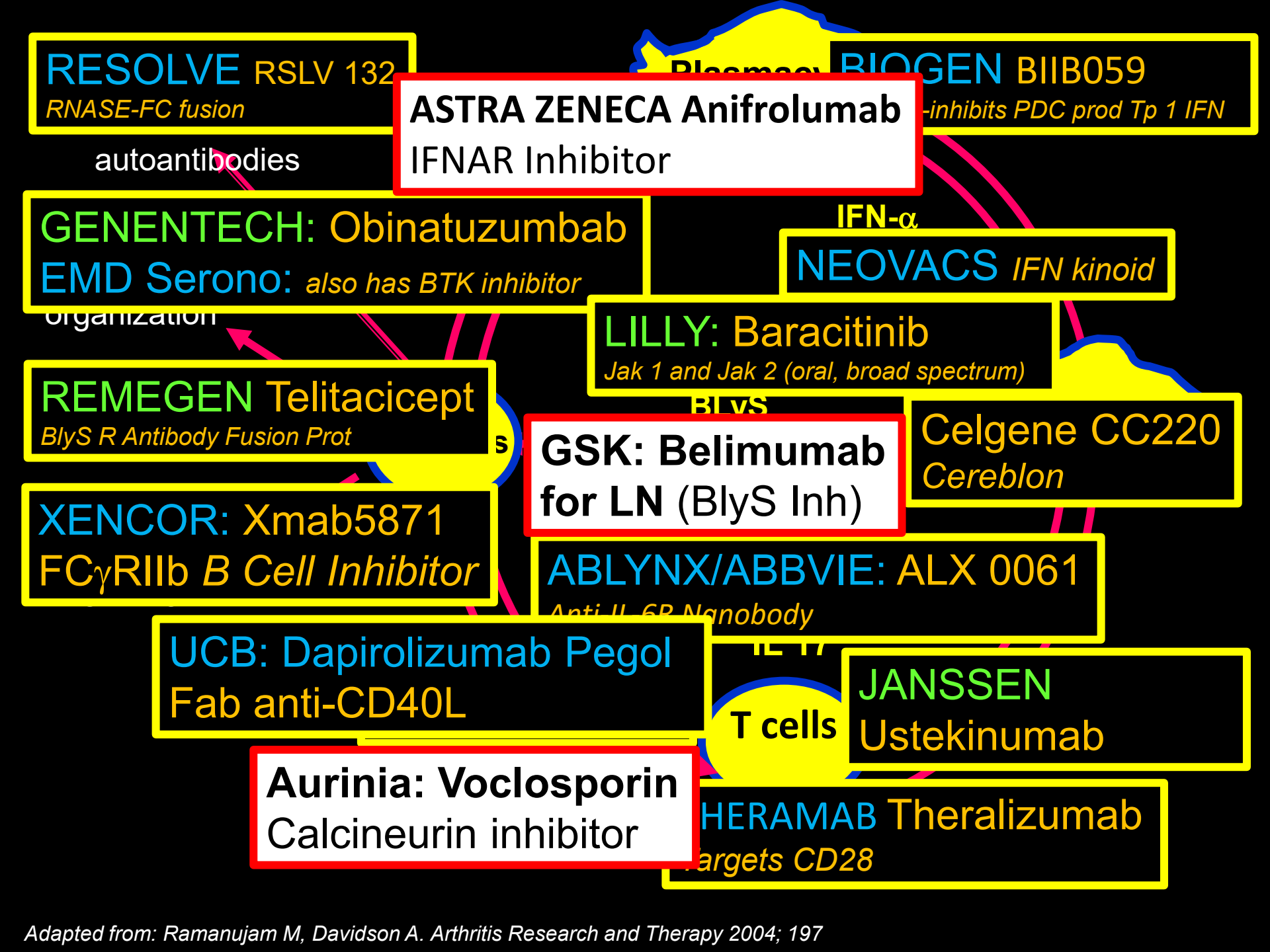


Adapted from: Ramanujam M, Davidson A. Arthritis Research and Therapy 2004; 197

The Search Continues

- The good news is that these disappointments have not stopped many pharmaceutical and biotechnology companies from forging ahead.

- There are a number of new treatments for lupus being studied now. And we know a whole lot more about how to succeed at this. And some are succeeding, more than we ever saw in the old days….



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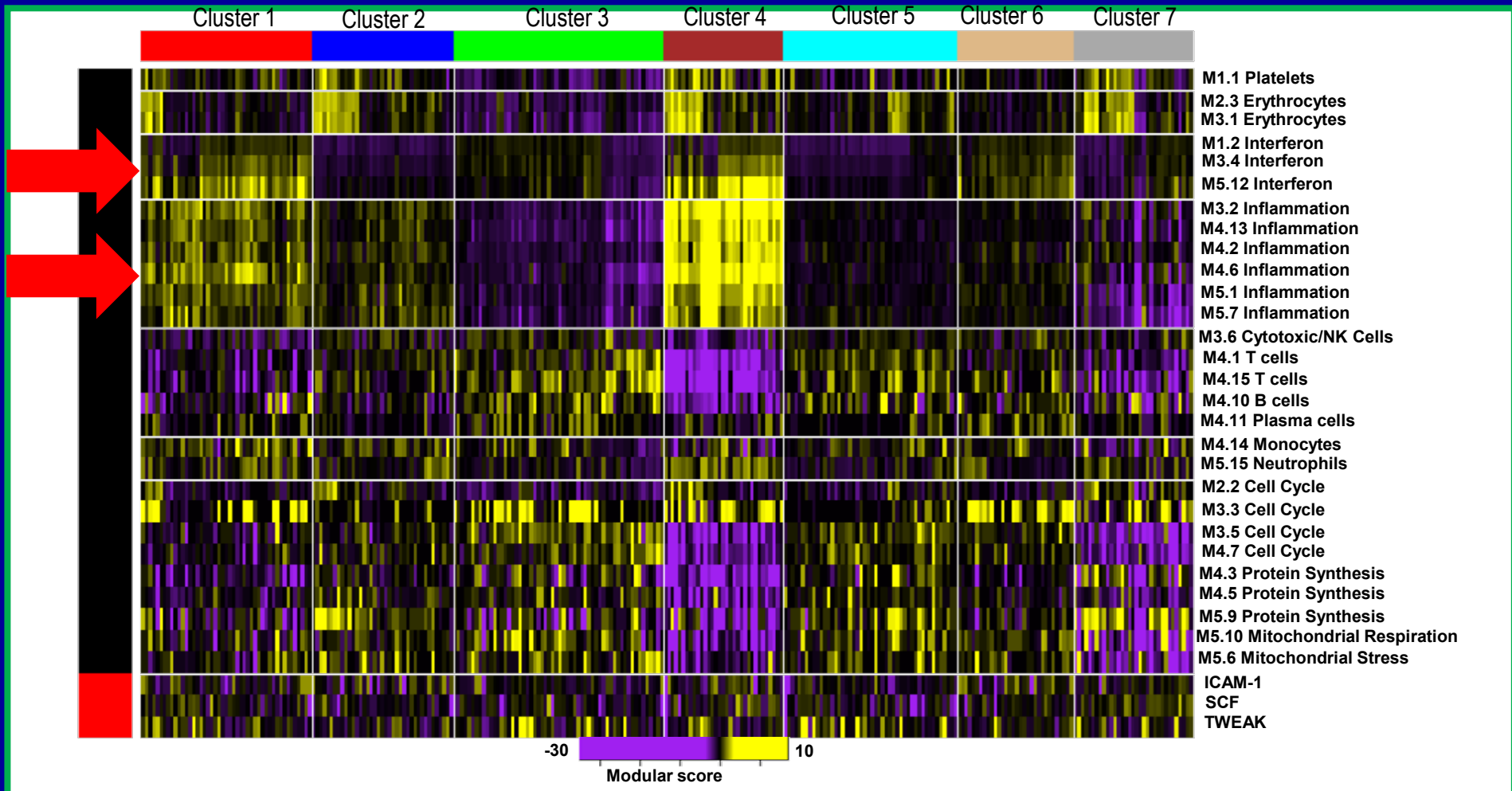
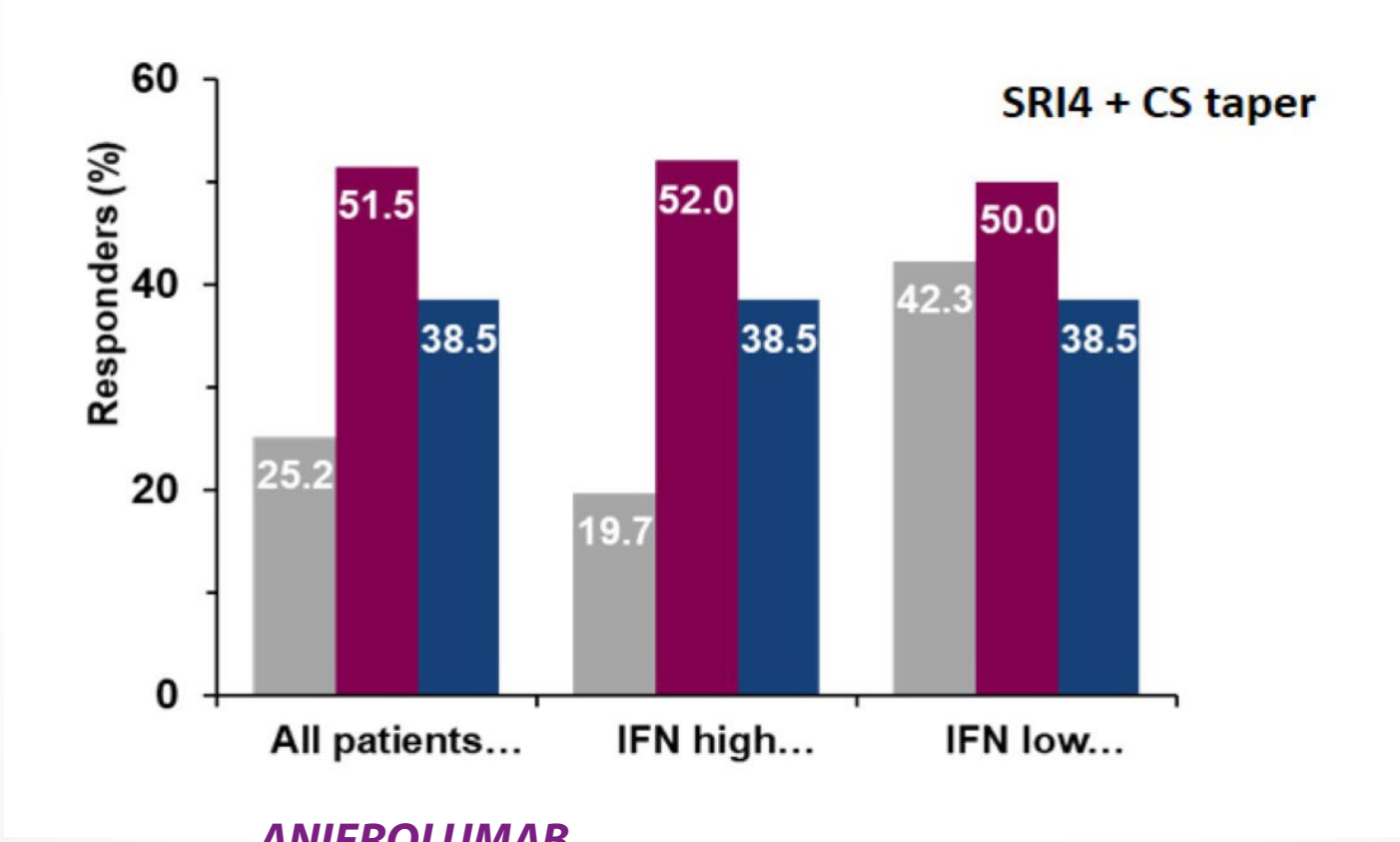
WHAT IS PRECISION MEDICINE?

Molecular Phenotypes of Individuals In Clusters:
Random Forest Modeling of Expression in Gene Pathway Modules



Lu et al ACR 2017

WHAT IS PRECISION MEDICINE?
IS IT REALLY HAPPENING?



ANIFROLUMAB

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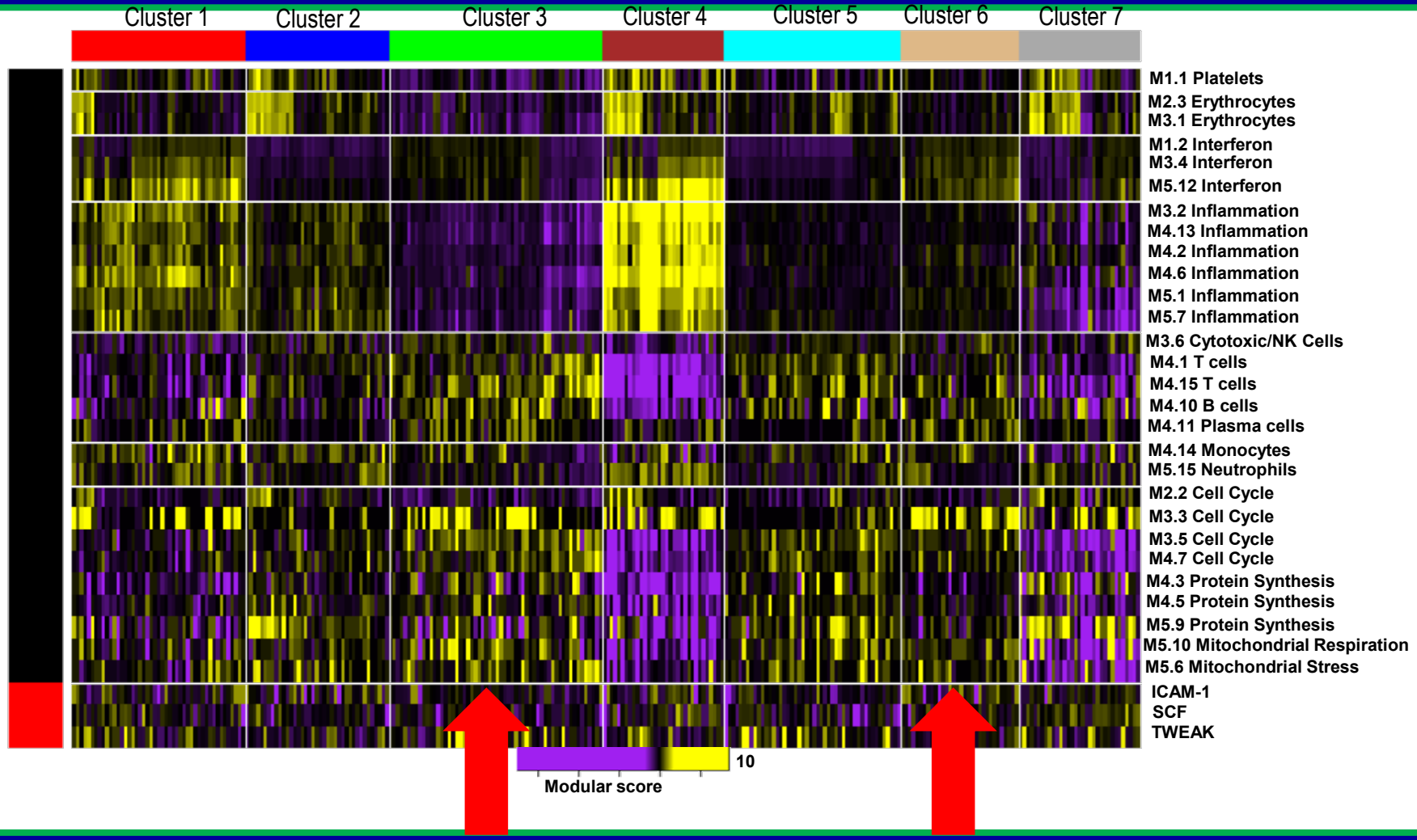
Furie Arthritis Rheumatol. 2017 Feb;69(2):376-386.
Merrill Lupus Sci Med. 2018 Nov 26;5(1):e000284.
Morand N Engl J Med. 2020 Jan 16;382(3):211-221

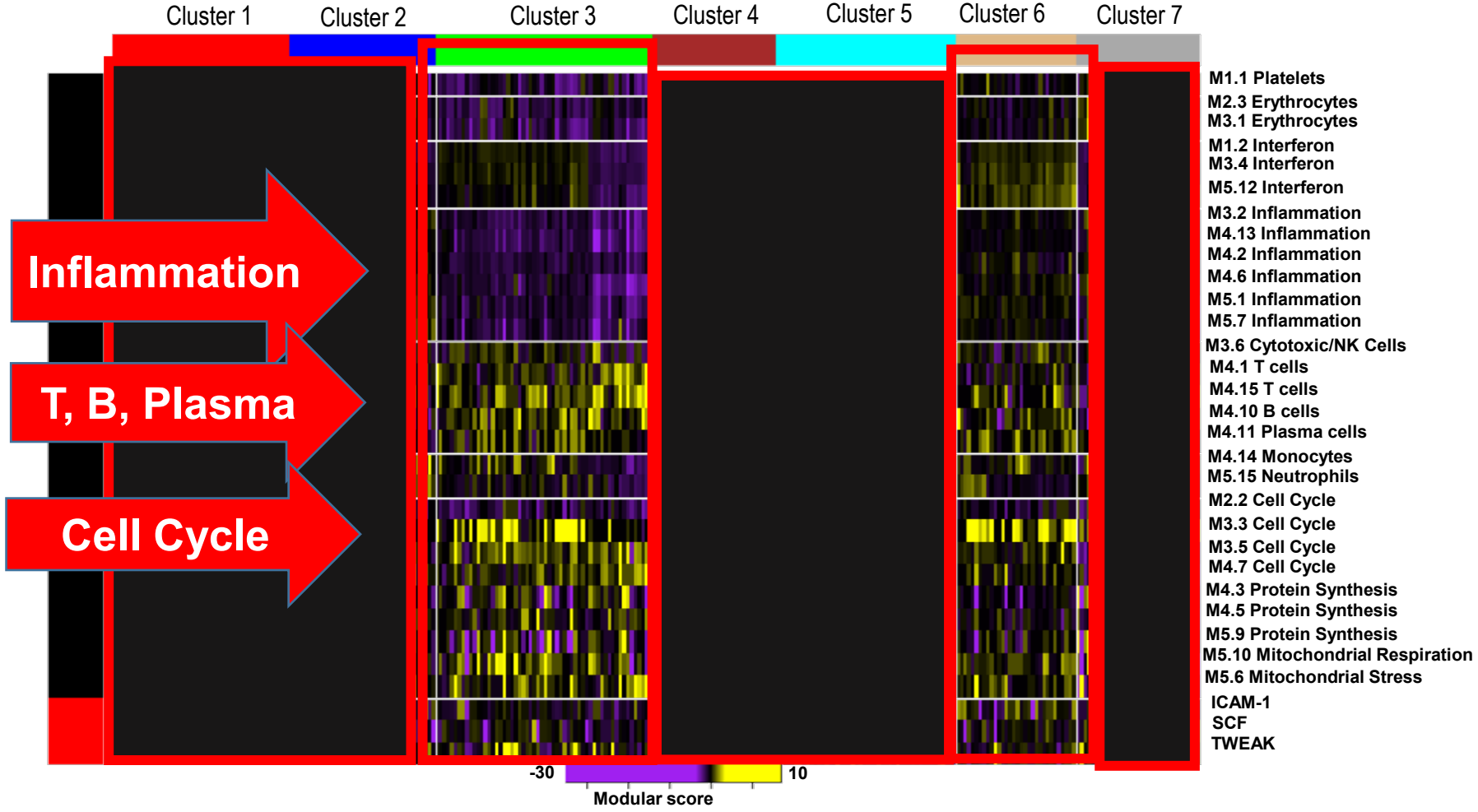
WHAT ABOUT THE OTHER PATIENTS?

Molecular Phenotypes of Individuals In Clusters:
Random Forest Modeling of Expression in Gene Pathway Modules



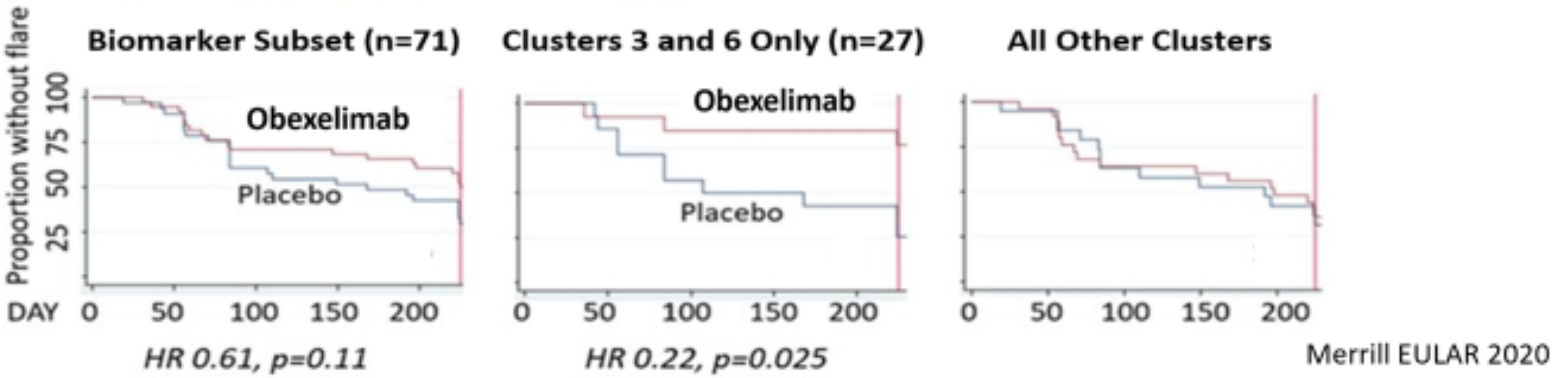
Lu et al ACR 2017

Molecular Phenotypes of Individuals In Clusters

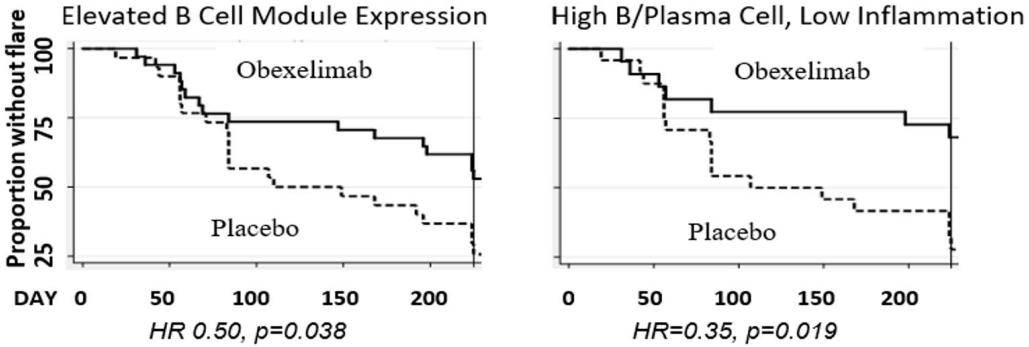


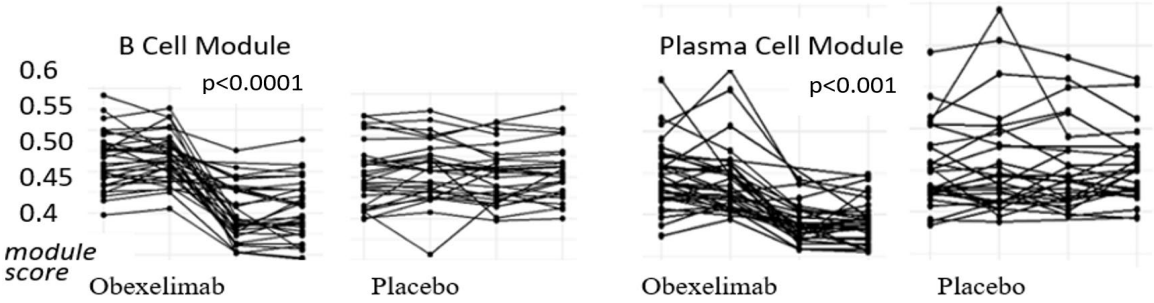
Lu et al ACR 2017

Obexelimab vs Placebo



Merrill EULAR 2020





Pathway Module Expression Over Time: Screening-Baseline-Next to Last-Last Visit

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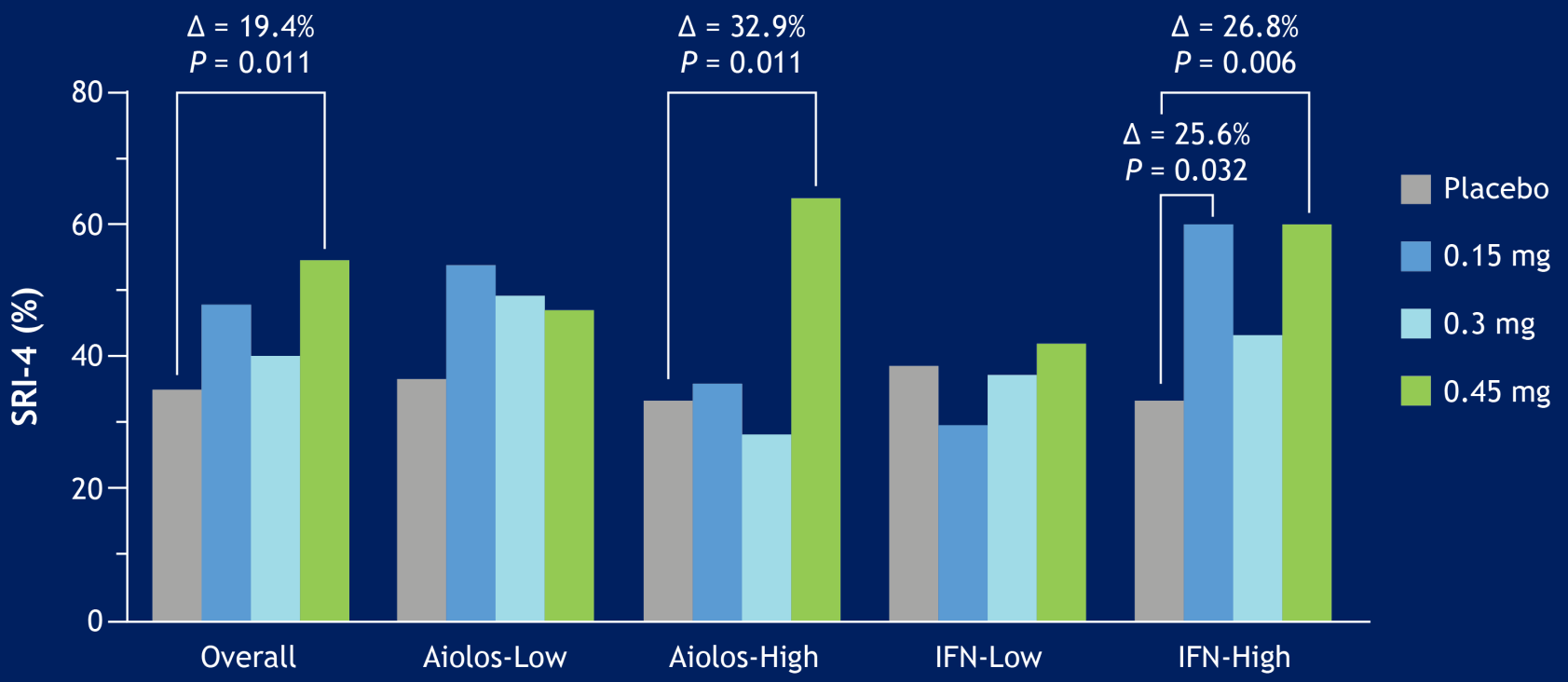
Merrill EULAR 2020

Iberdomide SRI-4 Response by Aiolos and Type 1 IFN Signatures

Proportion of patients improving at Week 24 of Treatment



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Merrill ACR 2020

Participation in Clinical Trials By People with Lupus is Needed or treatments for Lupus cannot advance

Each person who is invited to join a trial or who wants to look into joining a trial must be given proper information before deciding whether it is a good idea (or the right timing) for them to participate

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Part 2: Explaining the Process of Clinical Research: A Talk You Can Give

Clinical Research for Lupus: What You Might Want to Know

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To decide whether or not to participate in research a person needs to be:

- Comfortable with the process
- Empowered to make their own decision
- Fully informed

When people invite you to participate in research you should make sure:

- They are talking to you, not at you
- They are listening to you
- They are giving you information, not trying to convince you
- They know what they are talking about
- If you are uncomfortable you will speak up for yourself and, if necessary, stop the process

CULTURALLY COMPETENT COMMUNICATION

Am I only responsible for what I say?

….Not for what you hear?

National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS)

To provide effective, equitable, understandable, and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

How can we improve communication about research?

1. Provide complete, written information in language you can understand

2. Get advice and input from translators and community representatives, and access to language assistance from people who know the rights of research participants

3. Promote active “two-way” listening skills in order to:
   Identify communication mistakes more easily
   Empower you for discussions about research participation

Maybe patients who have been living with lupus should be helping to train research teams how to best educate them.

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PAST ABUSE OF RESEARCH PATIENTS

Research Safety

The Ancient Hippocratic Oath For Medical People:

Research Safety

The Ancient Hippocratic Oath For Medical People:

"First do no harm"

Does this mean we must take no risks?

Research Safety

Does this mean we must take no risks?

That's a problem.

To develop new treatments for lupus there will be some risk. But without new treatments for lupus, people will continue to have a poor quality of life, some will become disabled. Some may die.

"Risk Mitigation" means to make sure that risks are known, and that potential benefits outweigh the risks

How to Optimize Research Safety

1. Step by step treatment development

Phase 1

Single Ascending Dose

First just a few patients are given a tiny dose of the new treatment.
Then a few other patients are given a slightly higher dose.
This continues, gradually increasing dose, until…
A potentially effective dose has been tested and…
It seems to be well tolerated.

Multiple Ascending Dose

This is similar to the first idea, but now patients at each dose level are given more than one treatment. Studies are done to see how long the treatment stays in the body and if multiple doses are well tolerated.

Later Phases

The best dose and timing schedule learned from Phase I is given to more patients testing effectiveness and safety over time.

Research Safety

2. Patients must be active participants in studies, not "subjects"

<u>You must be fully informed</u>

What is the reason for the research?
What is the treatment expected to do?
What is known about side effects or other risks?
What do I need to do in order to participate?

Being informed includes the responsibility of the study team to tell you immediately if, during the study, any new information becomes available that might affect your willingness to continue participating.

Being informed also means having the study explained in a manner you are comfortable with and having all your questions answered.

Research Participants Rights and Responsibilities

You must be aware of your rights and responsibilities

Your responsibility is to try to follow the protocol, as long as you are doing OK, and as long as risks are acceptable to you

Your rights include the fact that you are free to stop research participation at any time with no loss of your legal rights or medical care benefits.

We Need to Know History

If you or family have heard something or read something that makes you worried about clinical research you have good reason

In the 1930's the **Nazi experiments** were cruel and often deadly to thousands of concentration camp prisoners

For 40 years between the 1930s and 1970s there was a study of African American men in Alabama. These men, most of whom were poor, were offered free medical care, meals and free burial insurance to participate in a study of the natural course of syphilis. 399 of these men started the study with syphilis. In the 1940s Penicillin became available and the people running the study did not explain this to the participants and did not treat them. This went on for decades. You can read more about this on the internet. It is called the **Tuskegee Syphilis Study**

In the 1960's **Thalidomide** was released in Europe without proper study and used by many women around the world for nausea during pregnancy. Many children were born with severe birth defects.

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https://history.nih.gov/about/timelines_laws_human.html
https://www.cdc.gov/tuskegee/timeline.htm
http://www.nytimes.com/2013/09/23/booming/the-death-and-afterlife-of-thalidomide.html

Over Time Things Changed

Timeline	Regulation	Description
1938	Food and Drug Act	Drugs must prove safe before marketing
1947	Nuremberg Code	Research should be scientifically necessary Conducted by qualified personnel. Animal studies precede human studies Benefit to science weighed against risks
1963	21 CFR 130.3	Informed Consent
1960s-1980s	Helsinki Declaration and revisions	Clinical research should follow animal and laboratory experiments. Conducted by qualified medical workers. Must weigh risks and benefits to the patient. Informed consent Unethical research should not be published
1974	National Research Act	Ethics Boards required to approve research
1970s-1980s	45 CFR 46 Subparts B, C, and D	Special protections for pregnant women and fetuses, prisoners and children
1979	Belmont Report	Respect: Human autonomy, informed consent. Beneficence: Research must be beneficial Justice: Benefits weighed against risk
Since 1990	International Conference on Harmonisation	Codified rules for Good Clinical Practice which puts the welfare of the individual trial participant ahead of the best interests of science

What is informed consent?

Research needs to be fully described to you in a way you understand, including the purpose of the research, what your role is, all the study procedures that are planned and the potential risks and benefits to you. All of your questions must be answered to your satisfaction.

There must be a written document that is approved by an ethics board, covering all of the information and your rights and responsibilities. You need to be given a copy of this whether or not you have decided to participate.

Before any research procedures can start, the informed consent document must be signed by the participant and a trained research representative at the site, showing that they both understand what the research is about.

Signing informed consent means you understand the research, and are participating with free will. It does not mean any commitment to continued participation, since the research participant may leave the study at any time by their own choice. Even a minute after signing the form!

Summary of How to Consider Participation in Clinical Research in a Way That is Comfortable for You

- Make sure that whoever is describing the study to you gives you a written summary of the study (informed consent document) that covers what the research involves, what your role would be, the potential risks and benefits, and your rights and responsibilities.

- The information must be written in language that you understand, and the study staff must spend enough time with you in a non-stressful environment so that your questions are answered.

- If you are not ready to make a decision and want to discuss this with friends or family, you should be able to take the informed consent document home with you.

ALSO….

- Remember that the proper job of research staff is to inform you of your options (including your options if you do not want to be in a study).
- Their job is not to persuade you to choose one way or another. If any of this feels wrong, do not proceed.
- When participating in research seems right for you, know the significance of your contribution. There will be no progress without research participants.
- Know your rights, including the right to respectful treatment, the right to being kept fully informed, and the right to change your mind about participating.

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Clinical Trials Part 3: Projects

https://empower.crisalisllc.com/empower

CLIMB

CLIMB: Connecting People with Lupus to Improve Meaningful Benefits from Trials

EMPOWER

Educating My Patients On Ways to Safely Engage in Research: The EMPOWER Project for Lupus

Study Population

Participants: Total = 212	Number	# (%) taking Pre-Test	# (%) taking Post-Test
HCP (95% male)	91	88 (97%)	61 (67%)
MD/DO	78		
NP/PA/RN	12		
Dct of Phys Therapy	1		
Non-Medical	121	63 (52%)	93 (77%)
Lupus Patients	99		
NS non-medical	22		

Descent/Ethnicity of 99 SLE patients

50 European, 23 African, 14 American Indian, 5 Asian 7 N/A

9 identified as Hispanic: 6 European, 1 African 1 American Indian and 1 N/A

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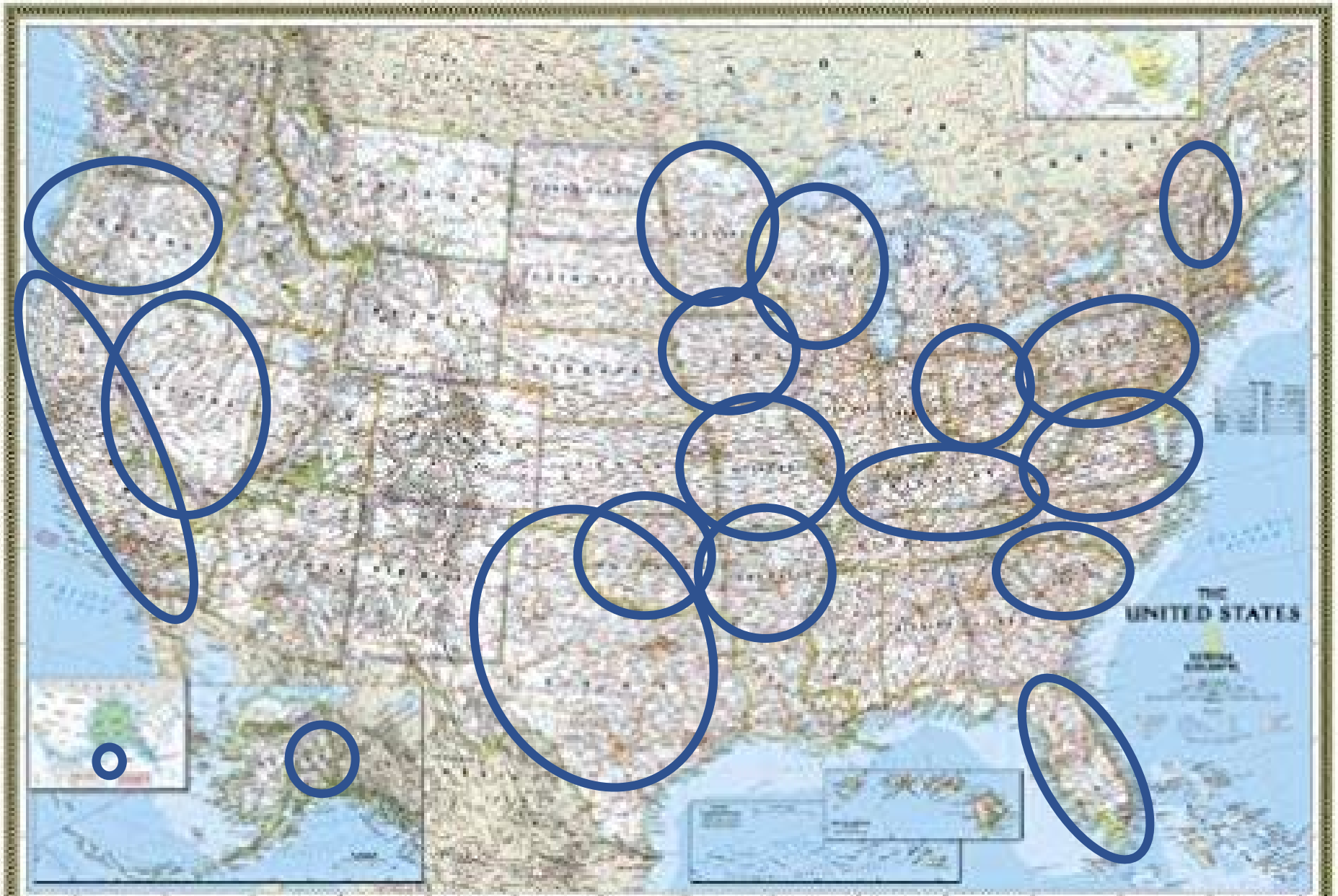
Arriens et al ACR 2019

Three Medical Service Areas in OK: Oklahoma City, Tulsa, and Lawton


THE
UNITED STATES

We Are Collecting Zipcodes……




CANADA
RUSSIA
NORTH ATLANTIC OCEAN
PACIFIC OCEAN
BRAZIL
SOUTH ATLANTIC OCEAN
INDIAN OCEAN
AUSTRALIA
THE WORLD

Study Population

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Arriens et al ACR 2019

All of the Following Are Important To Understand Before Taking Part in Clinical Research EXCEPT

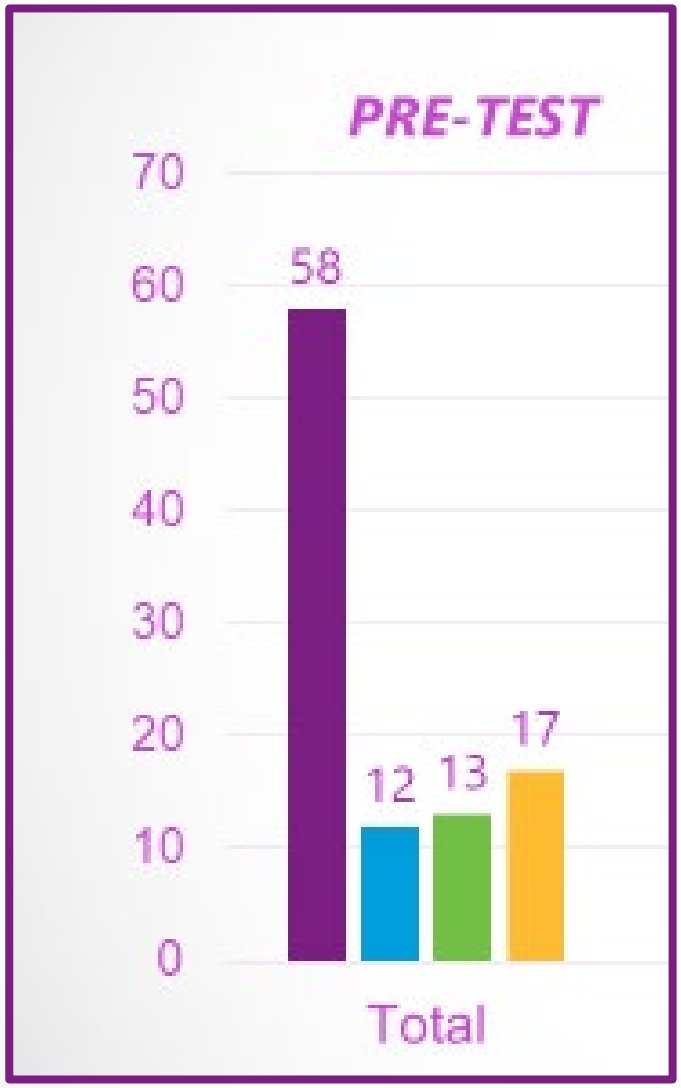
1. Informed consent is a commitment to follow the protocol even when you no longer want to

2. Knowing what side effects or other risks might be

3. Understanding what participation involves

4. Understanding why the study is being done

All of the Following Are Important To Understand Before Taking Part in Clinical Research EXCEPT



1. Informed consent is a commitment to follow the protocol even when you no longer want to

2. Knowing what side effects or other risks might be

3. Understanding what participation involves

4. Understanding why the study is being done

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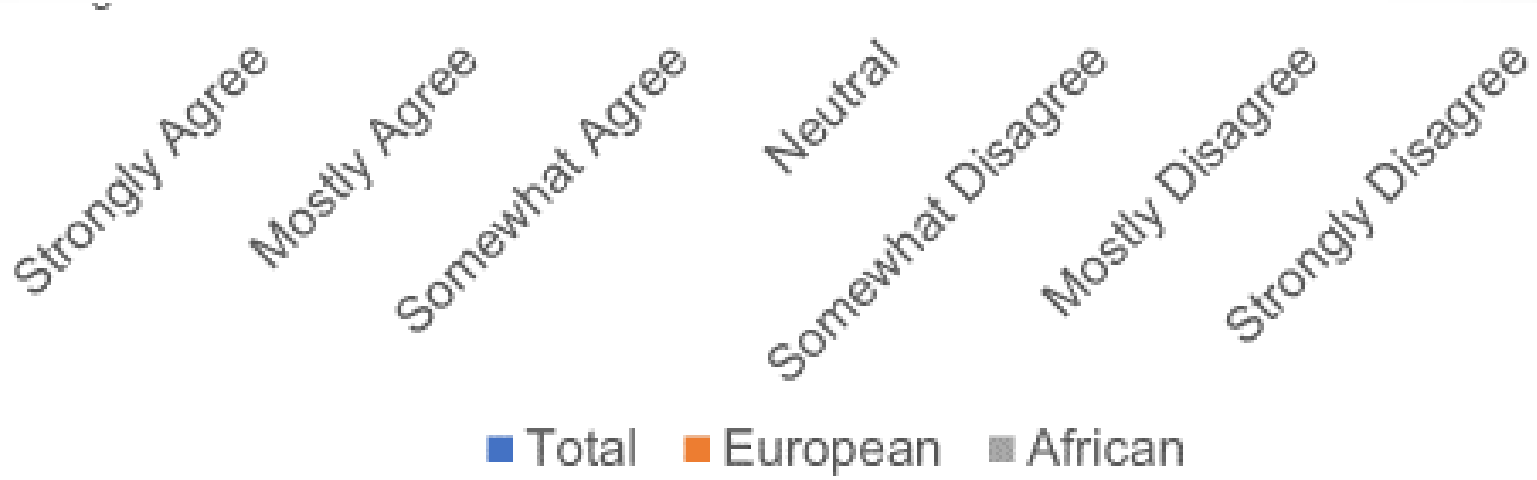
I would feel more comfortable learning about clinical research from someone who comes from the same background as me



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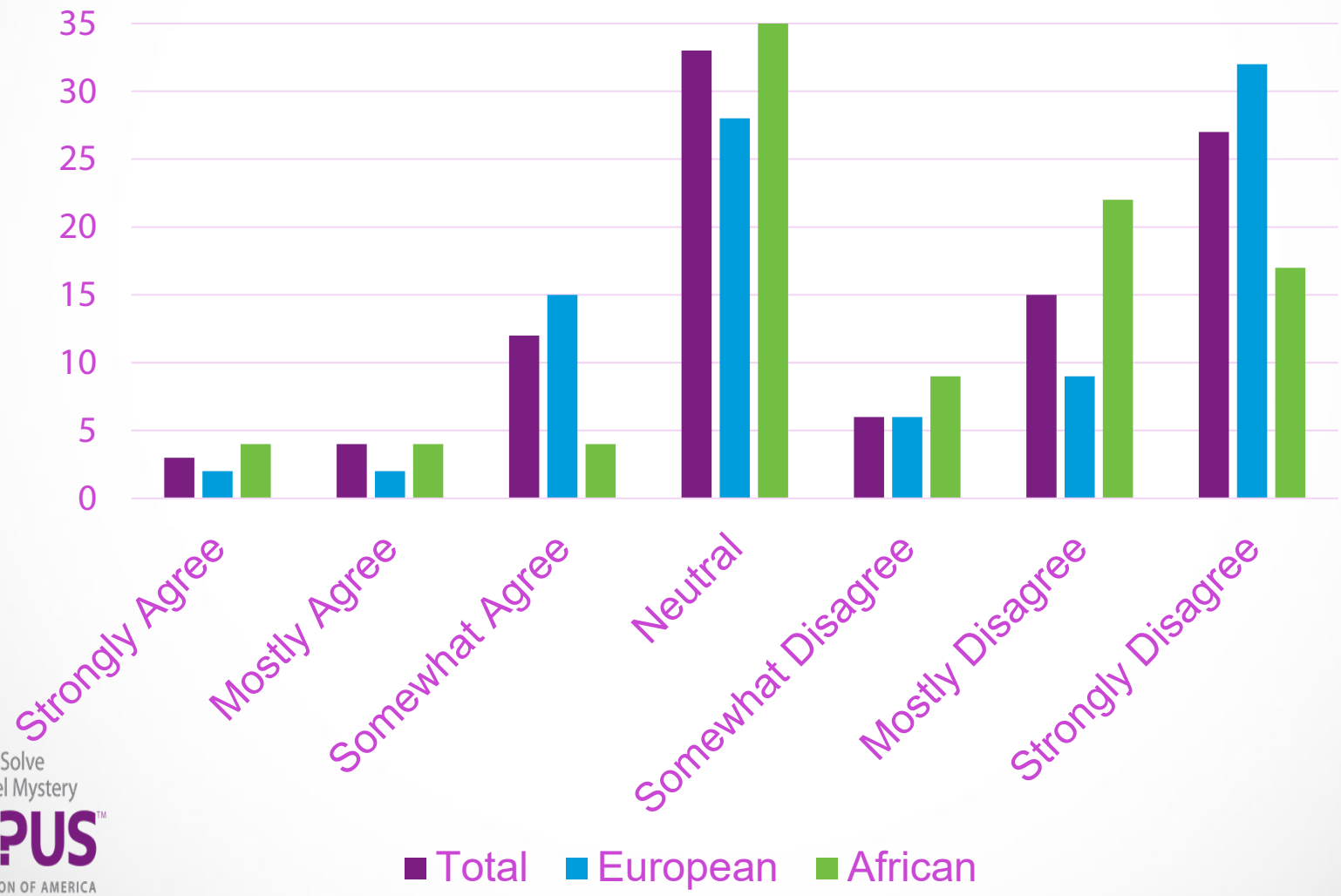

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Does Poverty Affect Ability to Follow a Trial Protocol?

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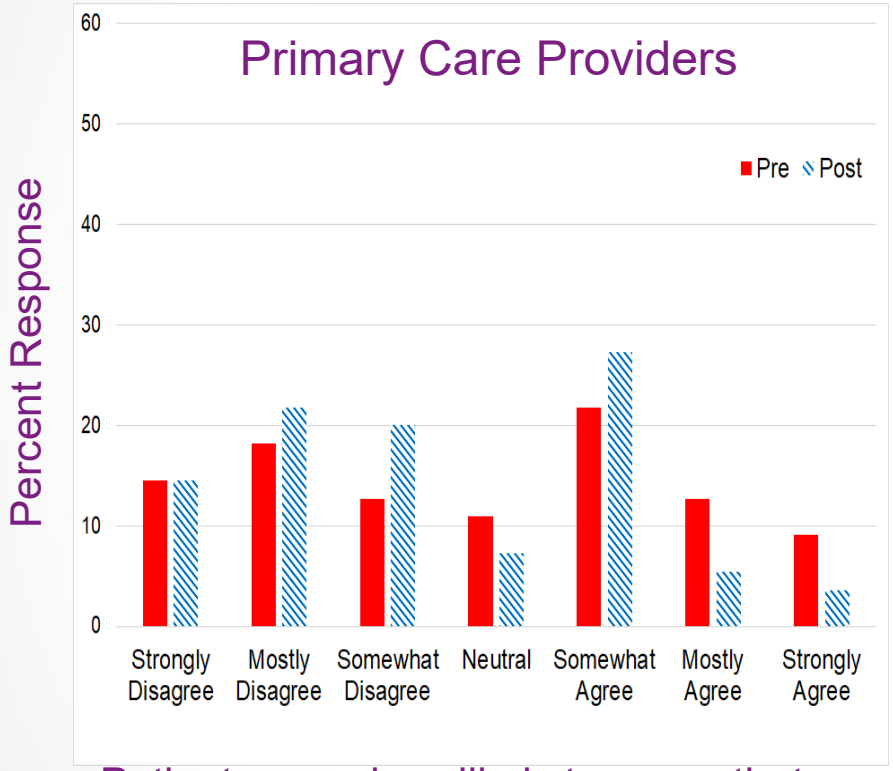

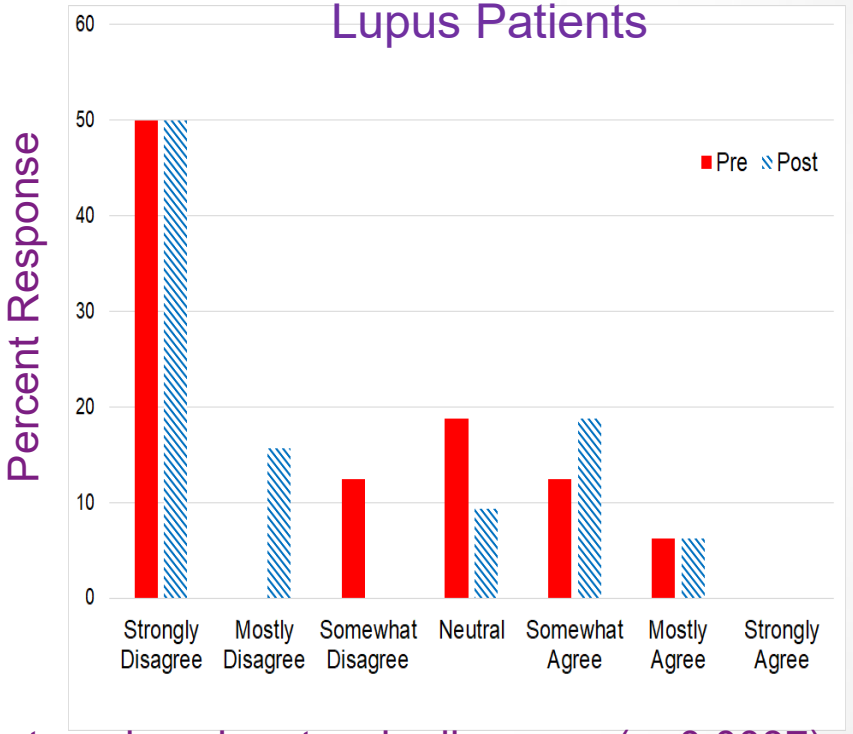

Patients were less likely to agree that poverty reduced protocol adherence (p=0.0037)
Clinicians did shift towards less strong agreement after taking the program

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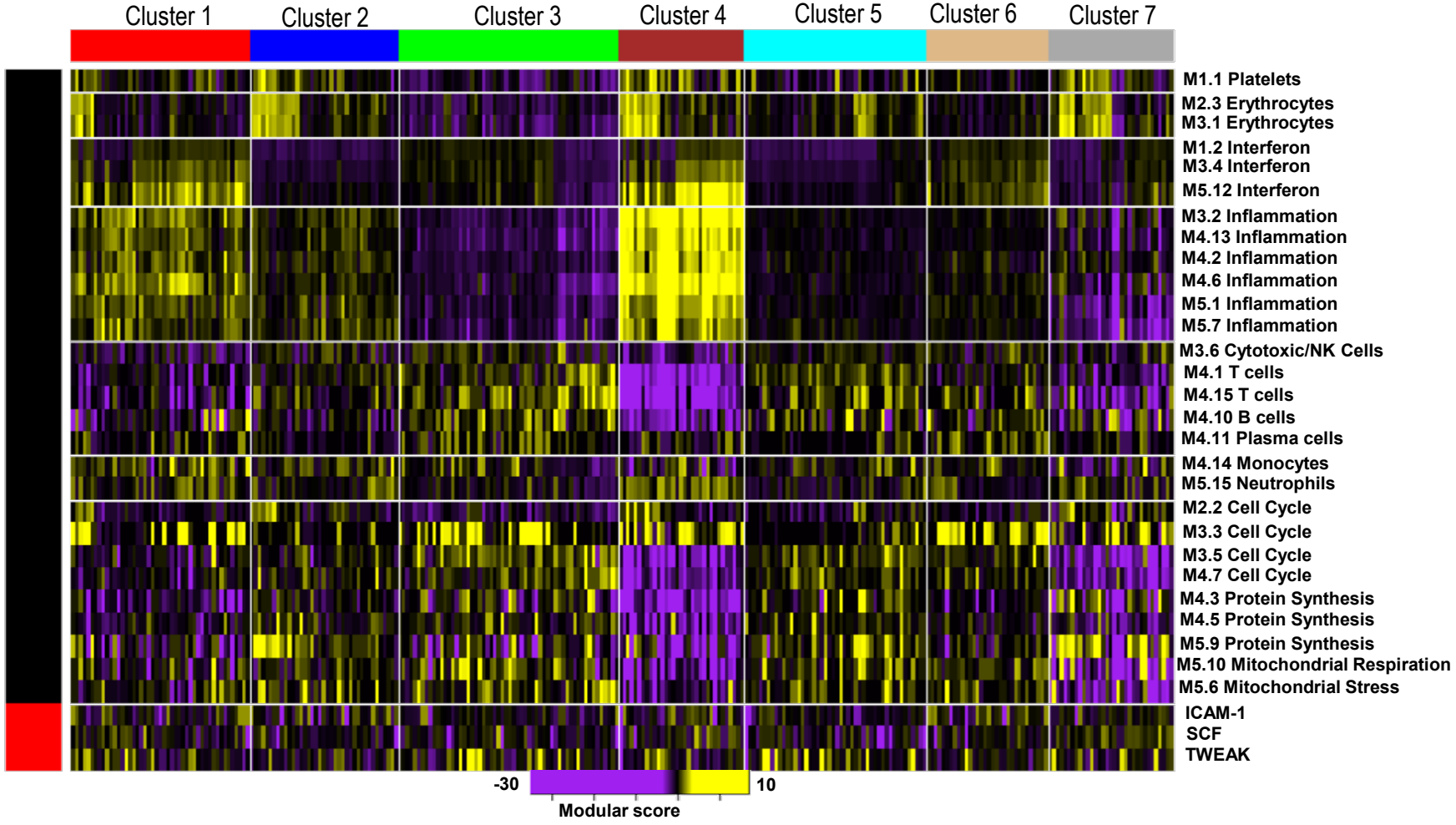
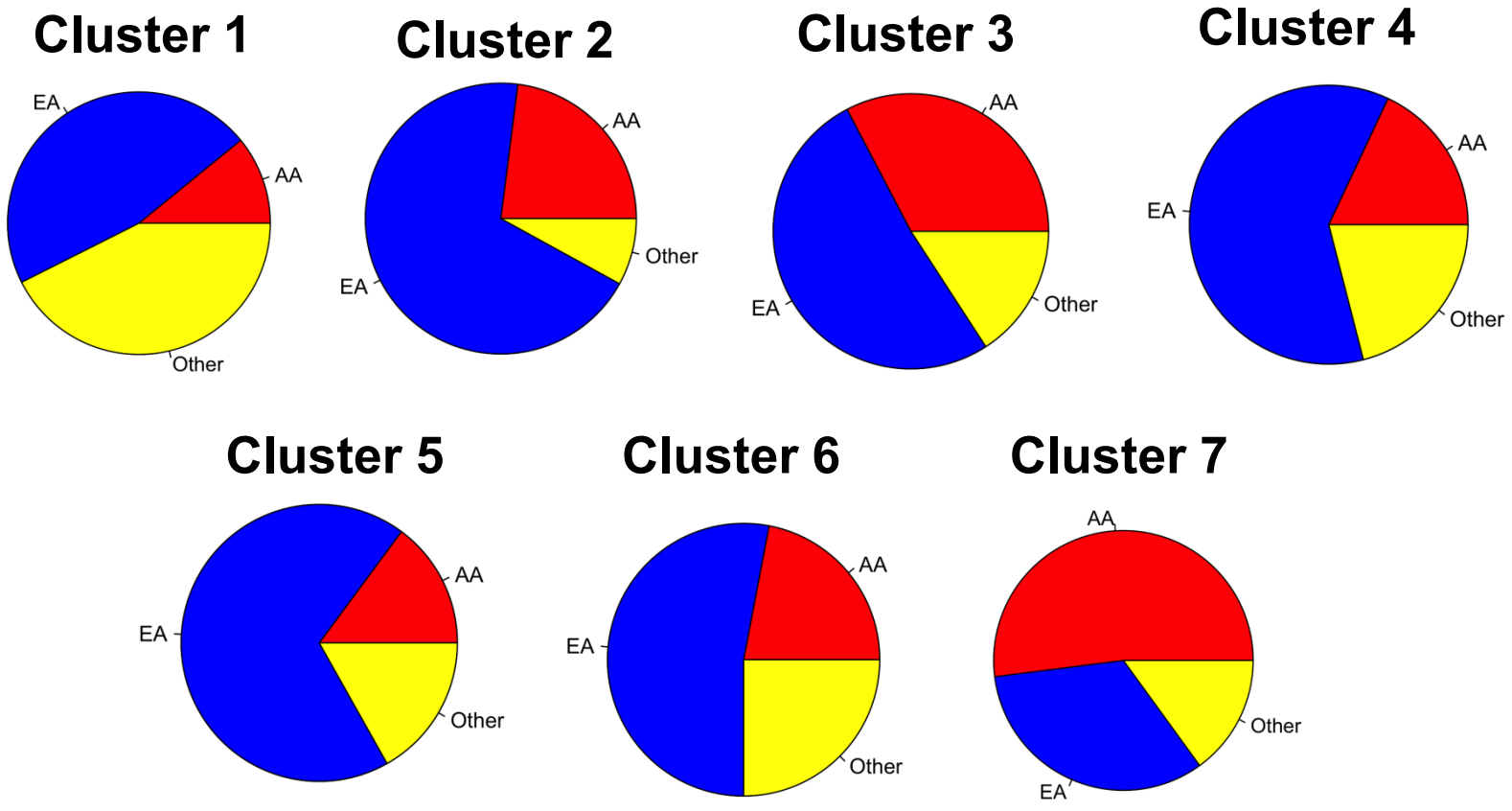
Molecular Phenotypes of Individuals In Clusters:
Random Forest Modeling of Expression in Gene Pathway Modules



Lu et al ACR 2017

Racial Distribution in Each Molecular Phenotype Cluster



Rewriting the Informed Consent

- The following slides have actual language used in informed consents for treatment trials
- In initial workshops, lupus patients and clinical trial staff have pointed out the following issues
  - What to call somebody who is participating in a trial vs what to call somebody who is considering it
  - How to meet government standards about talking about potential side effects, including death without needlessly scaring people
  - These are supposed to be written at a 6th grade reading level and often sound like legal documents. How can we merge legal disclosures with real talk
  - How to cover all required “elements of informed consent” without being 20 pages long and fine print

Can you help us rewrite this?

- Step 1: Get unbiased comments
- Step 2: See what people come up with as alternatives
- Step 2: Give the group a multiple choice based on the most common solutions they suggest

Actual Language From an Informed Consent

You are being asked to take part in a research study. Before you agree to be in this study, please read this consent form and ask as many questions as you need to be sure you understand the possible risks and benefits.

NATURE AND PURPOSE OF STUDY

You are being asked to participate in a research project called A Phase 2, Randomized, Double Blind, Placebo Controlled Trial of DRUGX in pateints with Systemic Lupus Erythematosus (SLE). The project has several goals:

1. To determine whether the study medication, DRUGX (also known as ExEximab) is safe and well tolerated in patients with SLE

1. To find out whether DRUGX is efficacious in reducing the signs and symptoms of SLE

This is a clinical study (a type of research study). Clinical studies include only subjects who choose to take part in them. Please take your time to make your decision. You might want to discuss this with your family and friends.

DRUGX is given as an injection right under the skin. The dose in each syringe is 100 mg which is exactly the dose that is given once a week. Some other substances are used to keep the treatment stable (these include water, sucrose and small amounts of some other agents (poloxamer 188, monobasic sodium phosphate, monohydrate, and dibasic sodium phosphate).

These agents help to keep the medicine at the same chemical balance (pH) that is found in the human bloodstream. The liquid that you receive in a syringe should not have any particles in it.

Adverse Events Associated with DRUG X

The most commonly reported adverse events in past clinical trials of DRUG X (found in more than 10% of subjects) are infections, upper respiratory infections, urinary tract infections, gastro-enteritis and herpes zoster (shingles). Less commonly, people taking DRUG X have experienced serious infections, cancer and death.

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In a year long study of 298 lupus patients with lupus kidney disease the adverse events were similar in the groups treated with DRUGX or placebo. Mycophenolate mofetil (Cellcept) was used in all of the patients along with significant steroids.

Infections were the most commonly reported adverse events. There was no difference in the numbers of infections in those taking DRUGX and those who only received MMF and steroids. There were more reports of gastroenteritis (symptoms in the abdomen with or without diarrhea) and shingles (herpes zoster) in patients treated with DRUGX compared to placebo. One patient developed a skin cancer that was not melanoma.

7 patients died during the study. 6 of these were related to infection (3 on placebo; 3 on DRUGX). The other death was due to a motor vehicle accident.

WHAT CAN WE DO TO PRO-ACTIVELY SUPPORT NEW SAFE AND EFFECTIVE TREATMENT DEVELOPMENT?

Obtain Informed Consent (volunteers only) to Take a Survey

Explain What Clinical Trials Involve

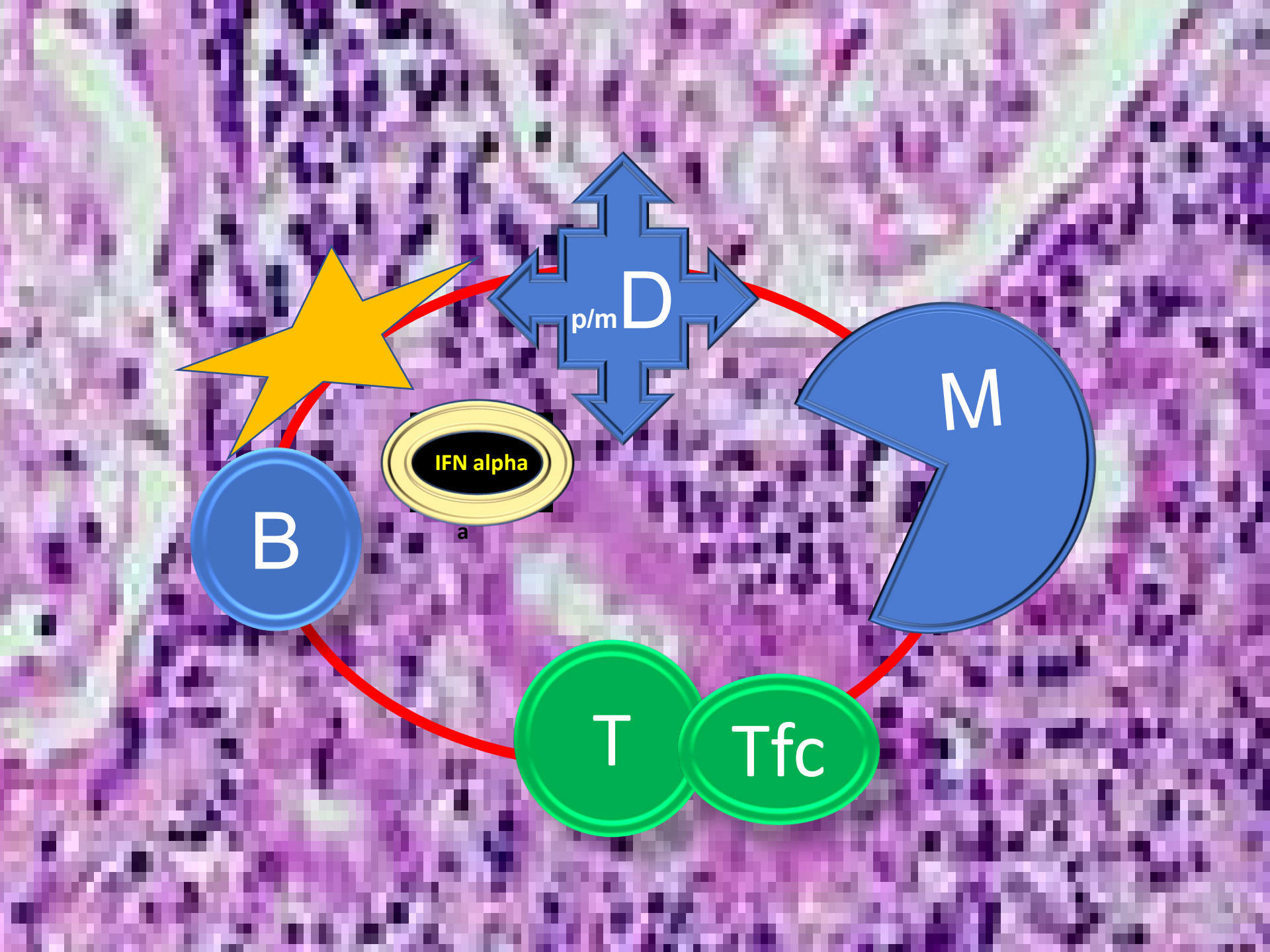
Patients Rights and Responsibilities

How to be an Informed and Empowered Research Participant

Survey of Experiences and Points of View about Benefits, Risks, Incentives and Impediments to Participating in Research

LFA: Potential Leadership in

- Patient Centered Outcome Measures
- Patient Developing Outcome Measures
- Patient Impact on Trial Design and Participant Empowerment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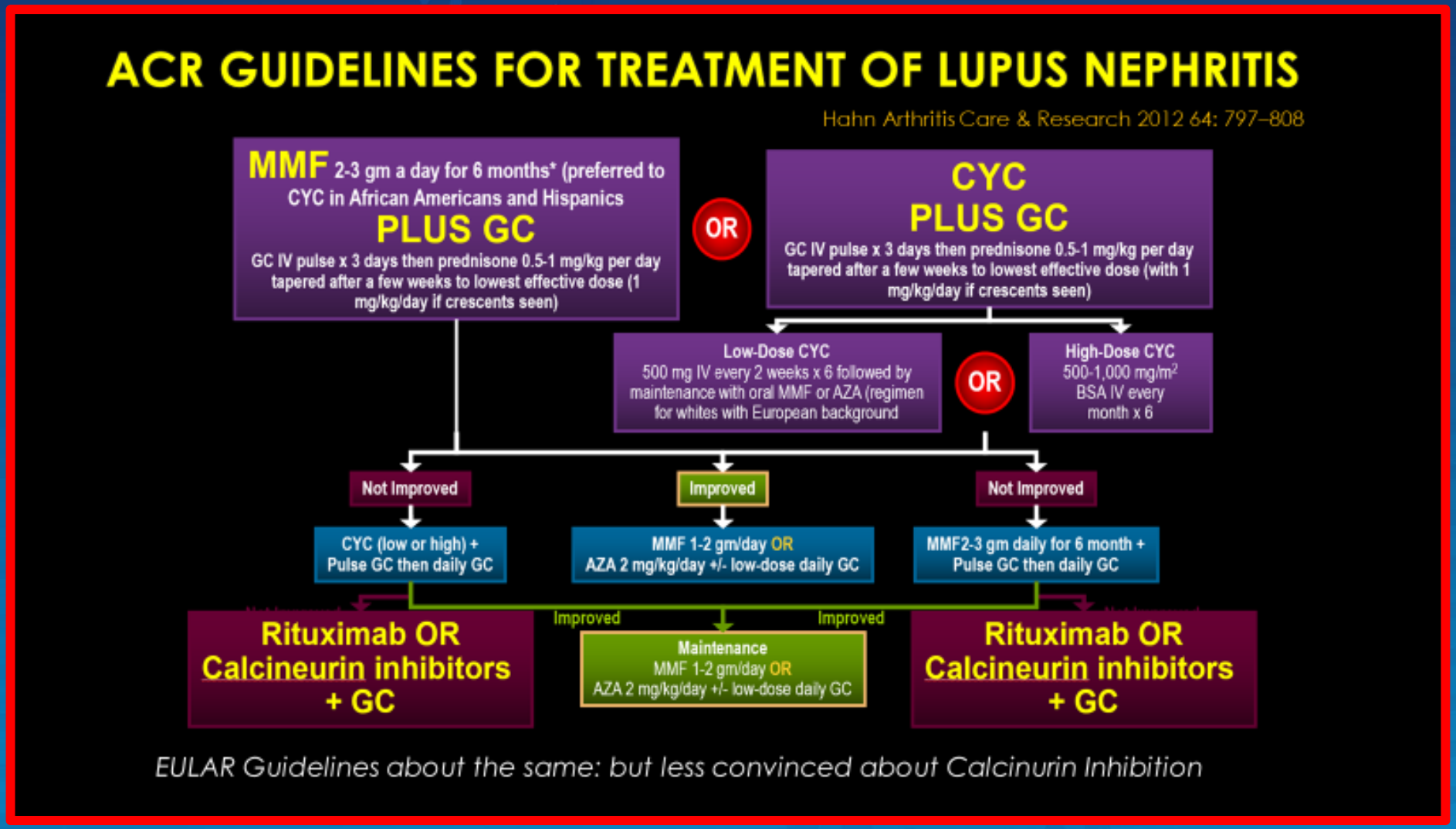
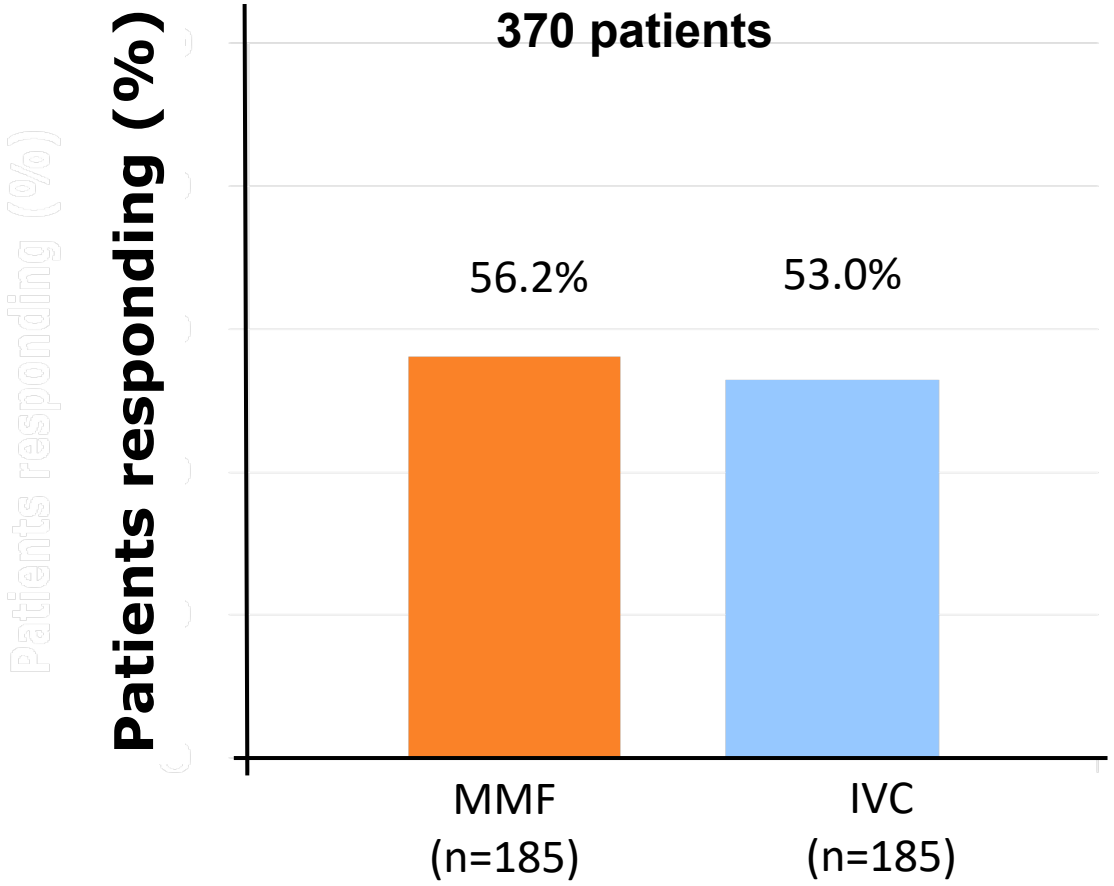
How Do Doctors Choose Treatments for Lupus Kidney Disease?

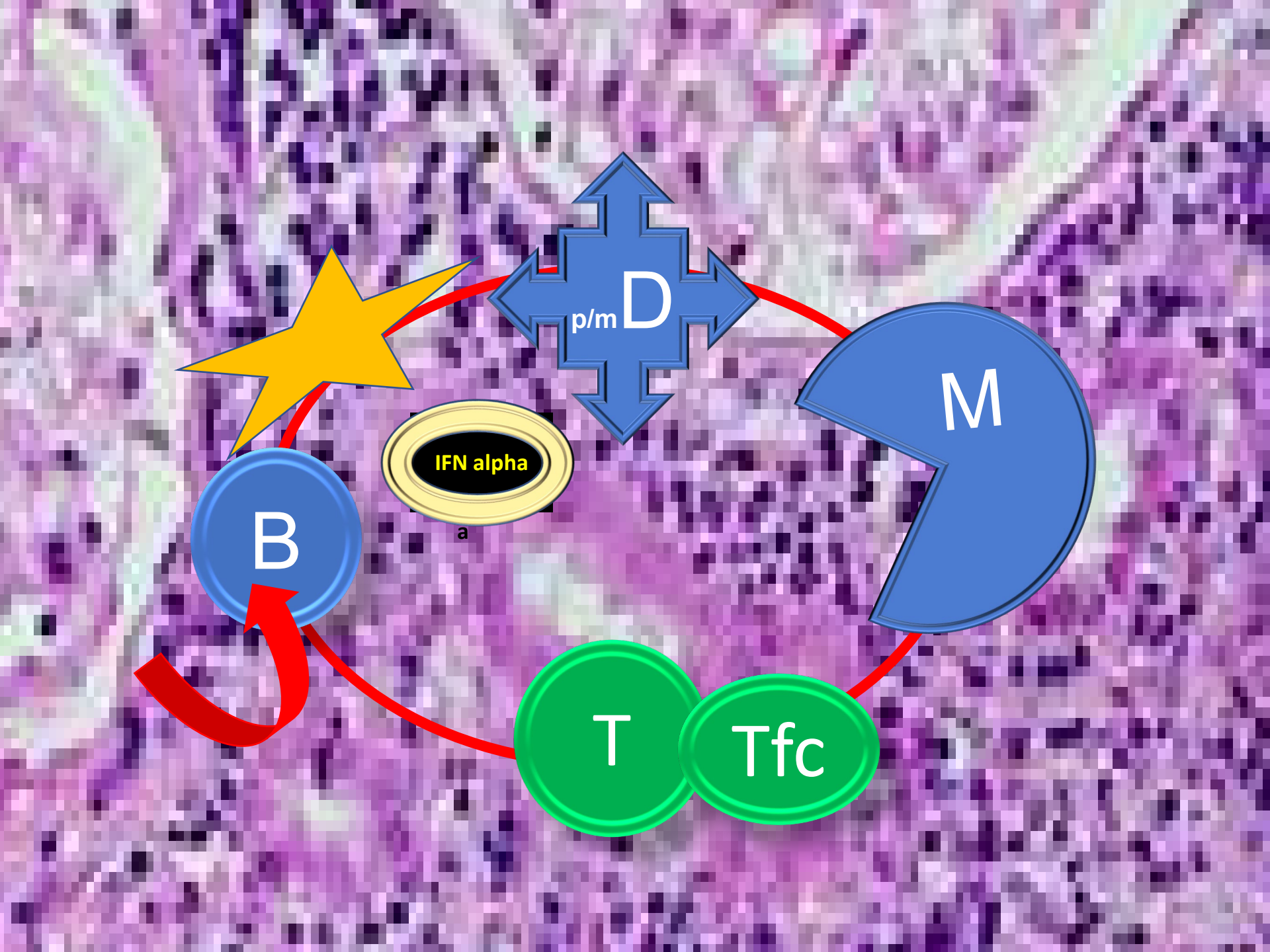


ALMS trial: MMF vs Cyclophosphamide



This trial did not require full improvement to be considered a response

Appel JASN 20:1103 2009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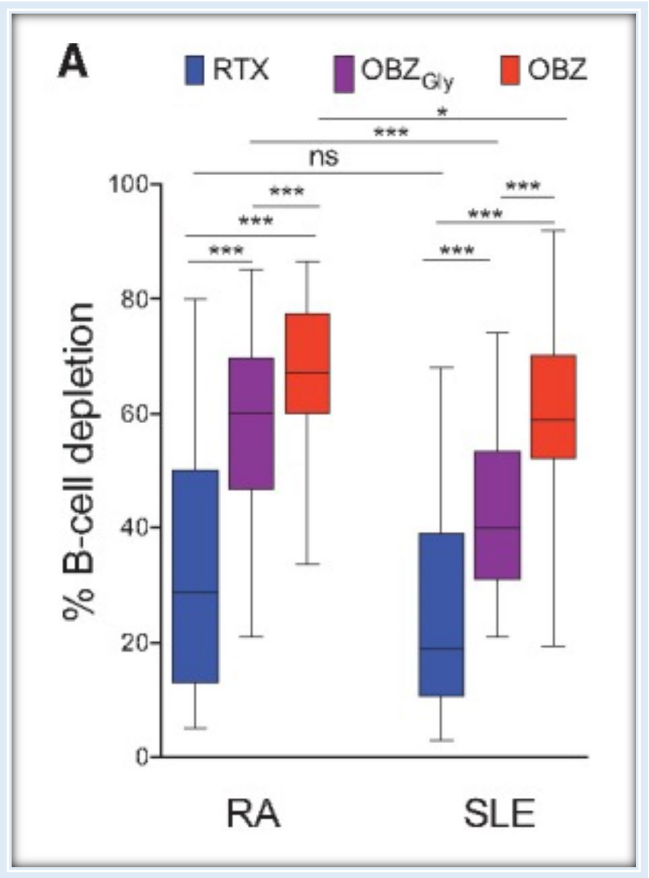


Obinutuzumab (anti-CD20)
Added to MMF
With Rapid Steroid Taper

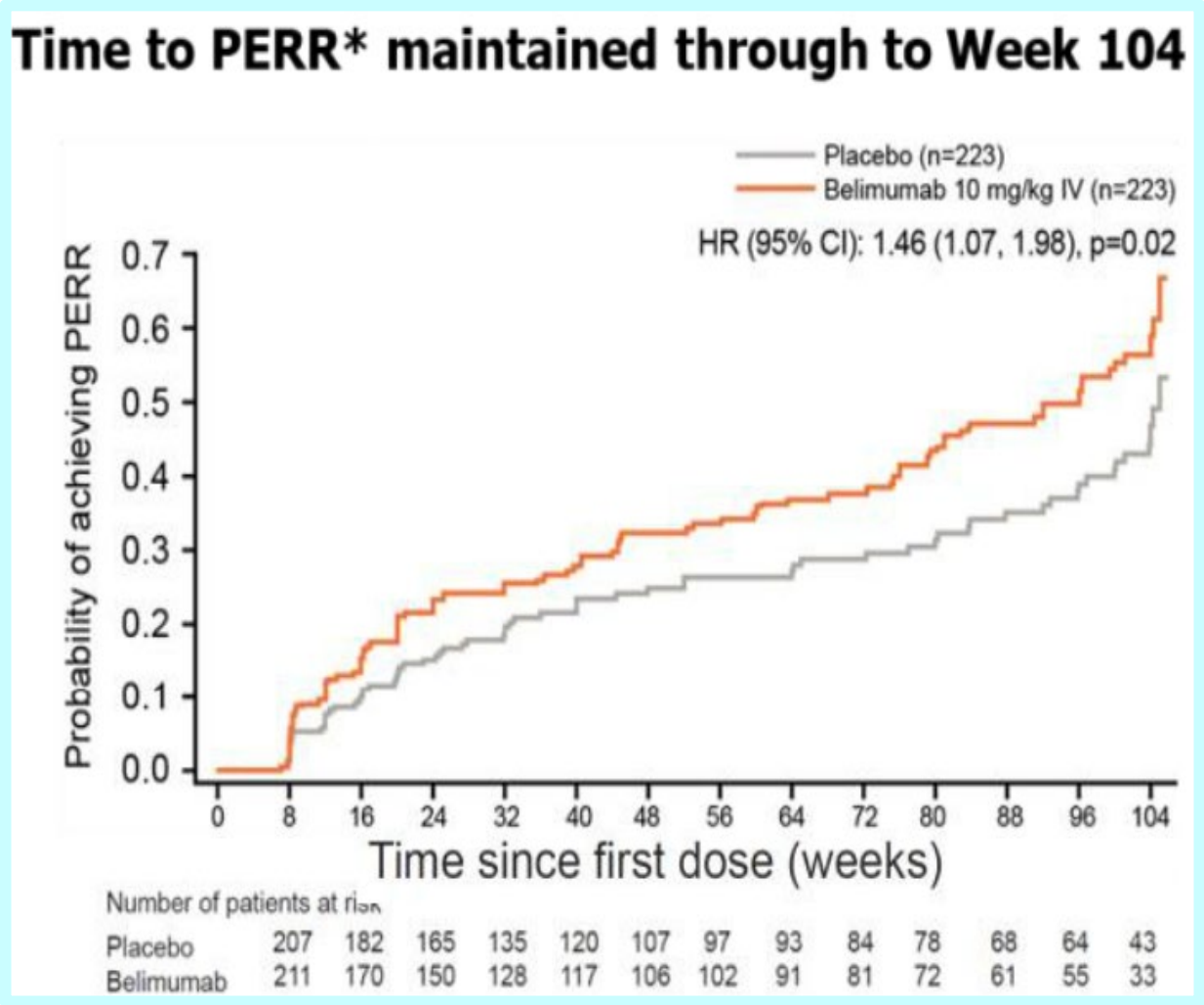
Table 1. Response Rates at Week 52

	Obinutuzumab + MMF N = 63	Placebo + MMF N = 62	Difference, % (80% CI)	*P* Value
CRR, n (%)	22 (34.9)	14 (22.6)	12.3 (2.1 to 22.6)	0.1145
Overall response (CRR or PRR), n (%)	35 (55.6)	22 (35.5)	20.1 (8.9 to 31.3)	0.0246
mCRR, n (%)	25 (39.7)	16 (25.8)	13.9 (3.2 to 24.5)	0.0900

CRR, complete renal response; mCRR, modified CRR, which excluded the urinary sediment criterion; MMF, mycophenolate mofetil; PRR, partial renal response.

PHASE 3 NEPHRITIS TRIAL OF BELIMUMAB ADDED TO STANDARD OF CARE

N= 448 pts 1:1 randomization (*MMF or CyC) + CS tapered to 10 mg by Week 24*

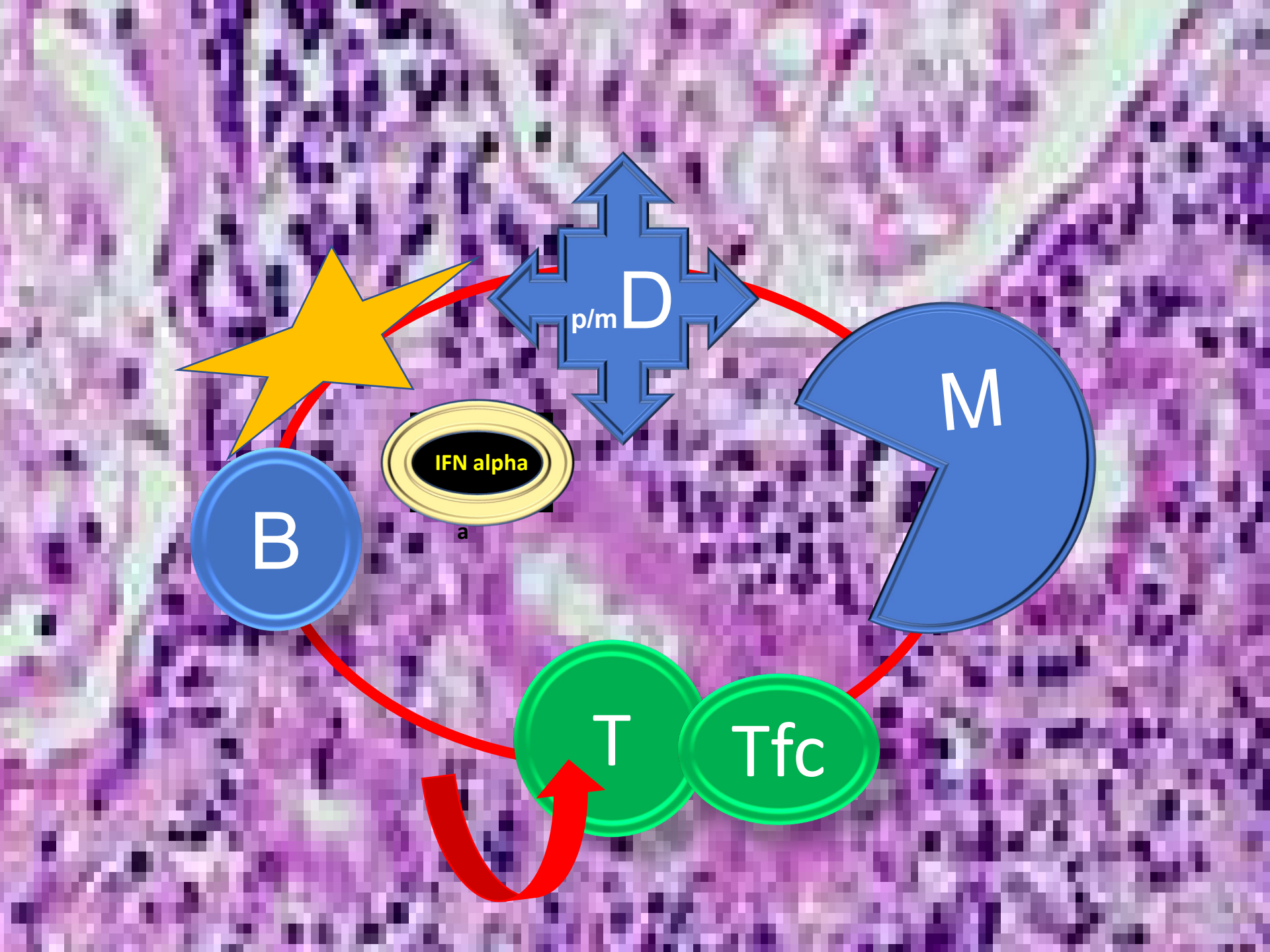


To Qualify: Class III, IV, V or mixed with uPCR >/= 1.0

Furie EULAR E-Congress 2020 OP0164

PERR: uPCR </= 0.7 eGRF </= 20% below pre-flare value or >/= 60 ml/min/1.73m^2 and not a treatment failure

CRR: uPCR </= 0.5 eGRF </= 10% below pre-flare value or >/= 90 ml/min/1.73m^2 and not a treatment failure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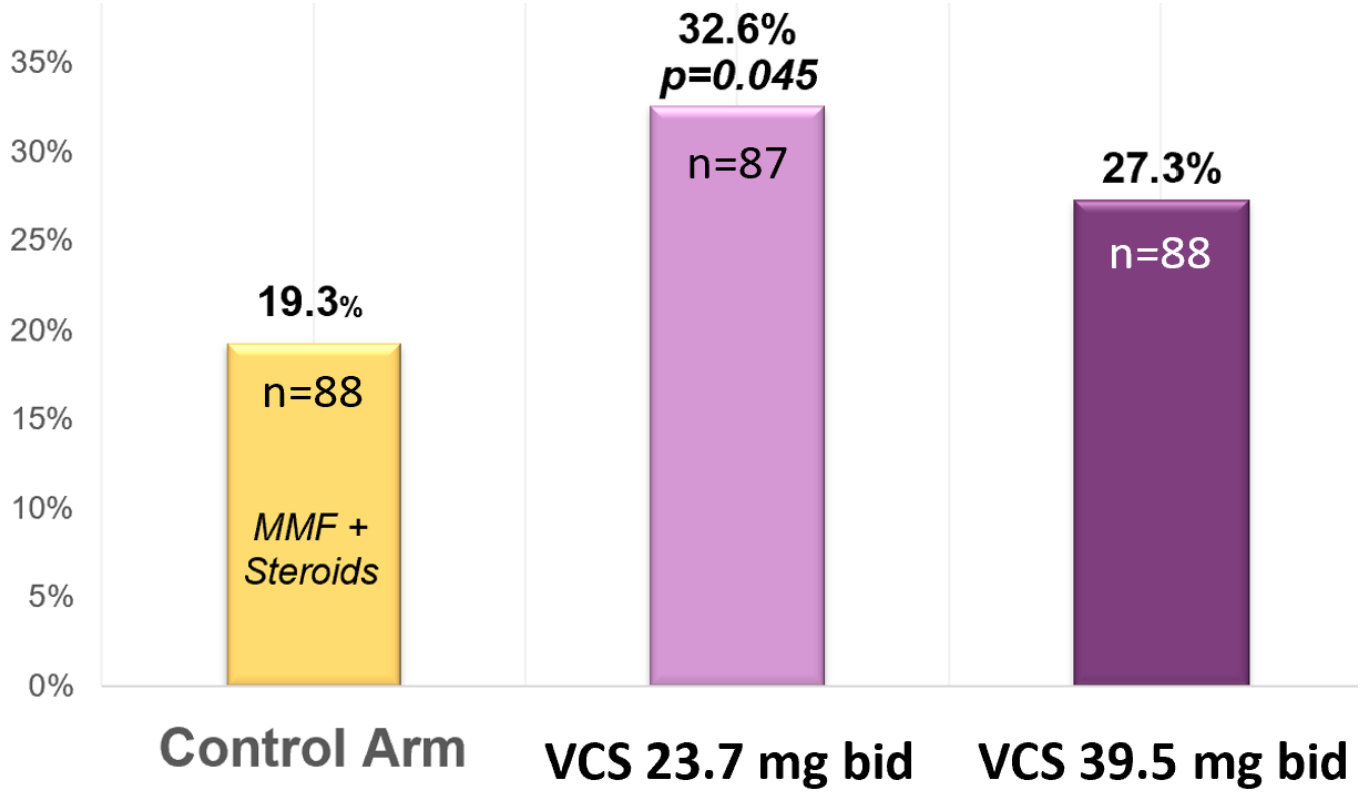
Voclosporin Phase 2 Study



SAFETY DATA	PLAC	23.7 bid	39.5 bid
% SAE	15.9	28.1	25
% Death	1.1	11.3	2.2

263 patients
Stringent Endpoint

Rovin Kidney International 2019 95:219

Phase 3 Voclosporin Trial Result

357 pts on MMF 1 gm bid rand 1:1 to VCS vs placebo with rapid OC taper

Endpoints	Measure	Result	Odds Ratio (95% CI)	p-value
Primary	Renal Response 52 weeks	Voclosporin 40.8% Control 22.5%	2.65 (1.64, 4.27)	<0.001
Secondary	Renal Response 24 weeks	Voclosporin 32.4% Control 19.7%	2.23 (1.34-3.72)	0.002
	Partial Response 24 weeks	Voclosporin 70.4% Control 50%	2.43 (1.56-3.79)	<0.001
	Partial Response 52 weeks	Voclosporin 69.8% Control 51.7%	2.26 (1.45-3.51)	<0.001
	Time to UPCR </= 0.5	Voclosporin faster than Control	2.02 (HR) (1.51-2.70)	<0.001
	Time to UPCR 50% reduction	Voclosporin faster than Control	2.05 (HR) (1.62-2.60)	<0.001

Primary endpoint similar to Phase 2 study

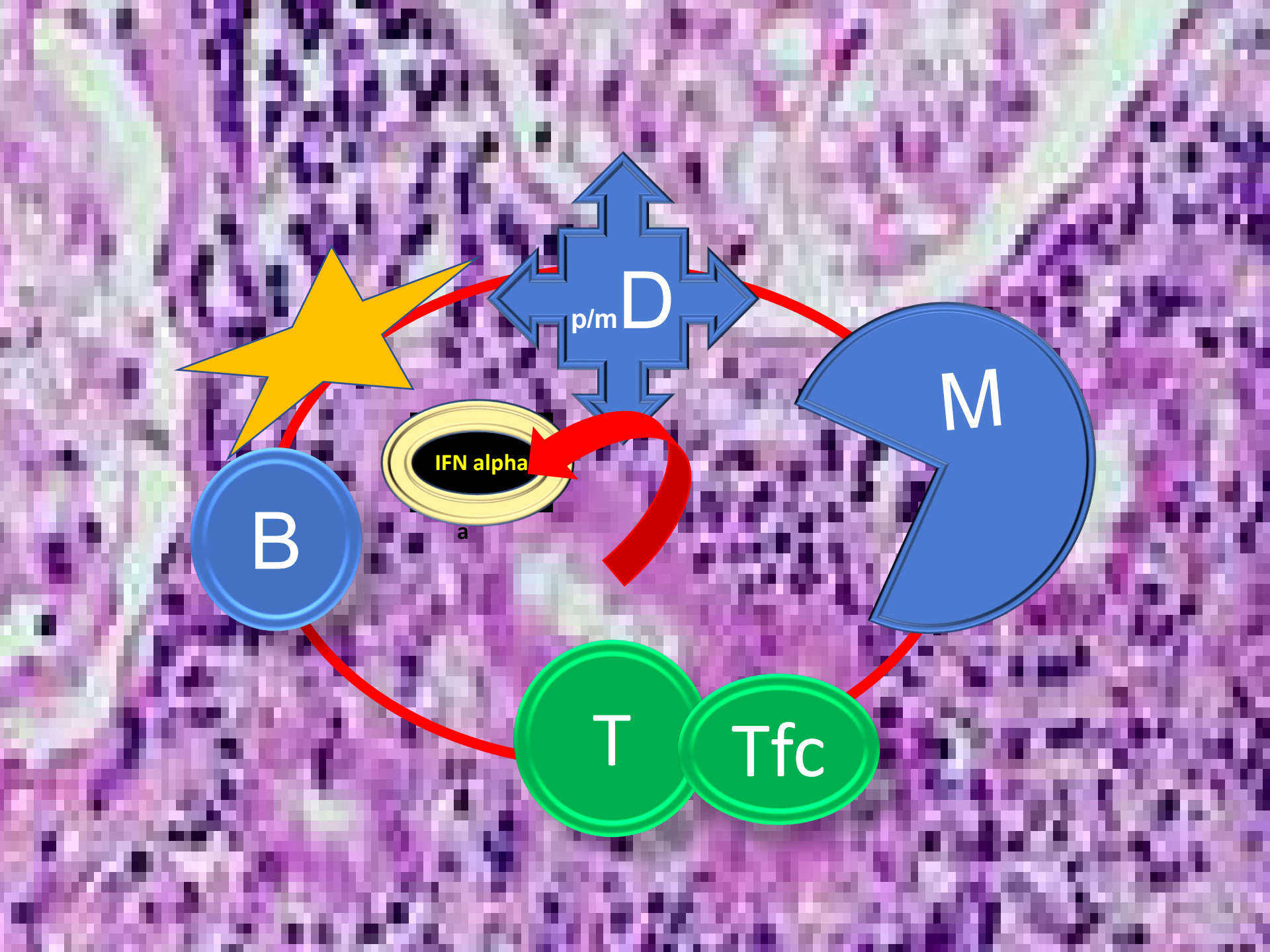
Arriens EULAR E-Congress 2020 OP0277

Brief Summary of Phase 3 Voclosporin Safety Results

	Placebo	Voclosporin
Serious Averse Events	21.3%	20.8%
Infection SAEs	11.2%	10.1%
Deaths	5	1

At Week 52 there were not differences in expected side effects with calcineurin inhibitors including eGFR BP, lipids, or glucose.

Arriens EULAR E-Congress 2020 OP0277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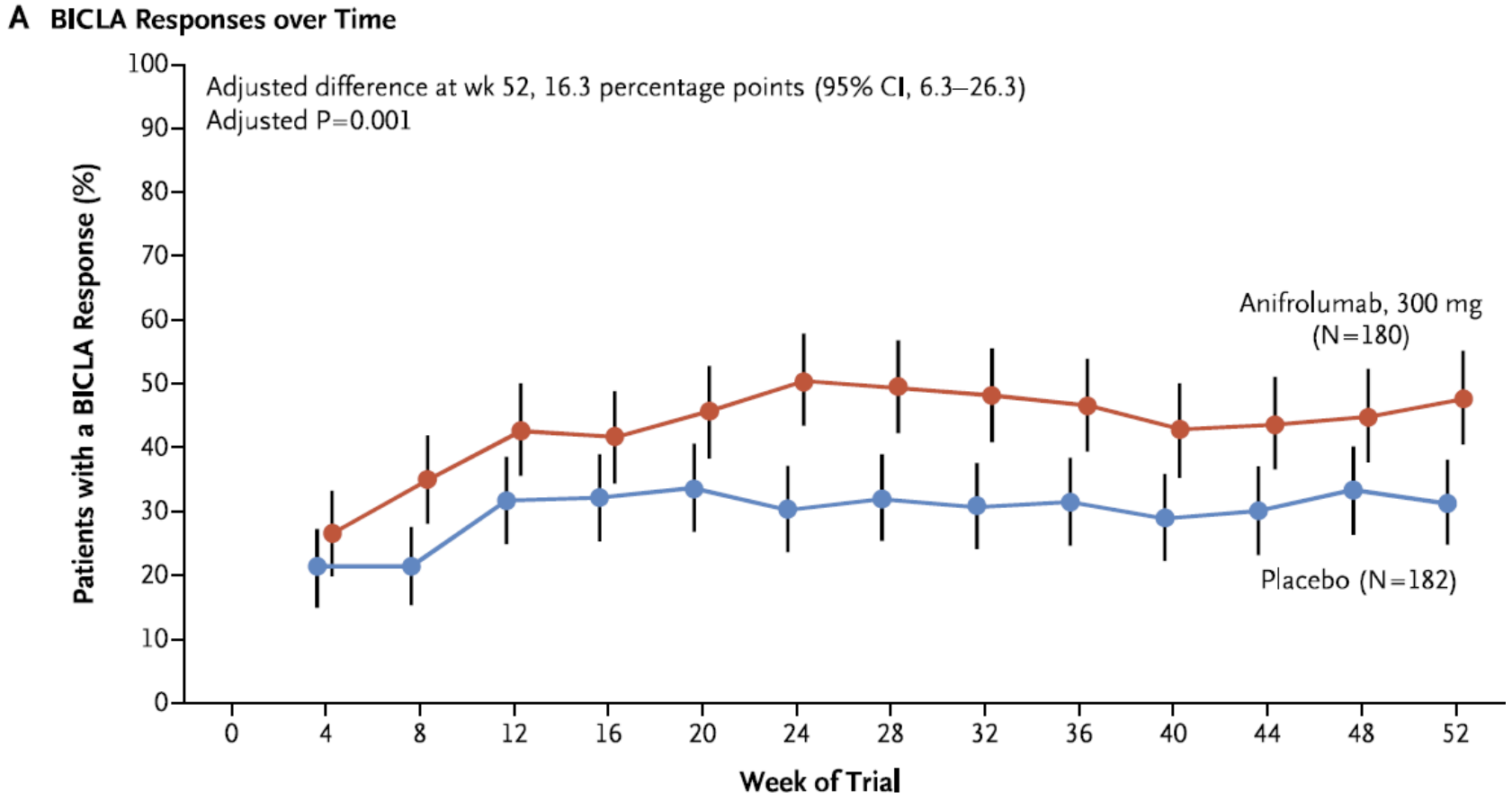
ANIFROLUMAB PHASE III TULIP TWO



Morand NEJM 2020 382:211

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Group Discussion:
Clinical Trials and Lupus Research

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Recap and Tomorrow

Tomorrow's Agenda, 10/27 4pm ET

- Recap of Day 1
- Hear from the Experts panel
- The Importance of the Patient Perspective in Lupus Drug Development and Clinical Trials
  - Patient Focused Drug Development
  - RAY: Research Accelerated by You
- Advocating to Support Research
- Speaking About Research
- Recap and Next Steps

Thank you