

Ongoing and future studies on vasculitis in Canada



1st CanVasc meeting – Toronto – 10 June 2011

Vasculitis trials and studies

- **Active in Canada**

- ARCHIVE
- PACNS registry
- VCRC longitudinal study
- GCA and MRI (McMaster – Khalidi)
- VCRC AGATA GCA/TA
- EUVAS/VCRC/International PEXIVAS
- VCRC one-time DNA + C. Siminovitch (Toronto)

VCRC longitudinal study

- **Hamilton, Toronto**
- **GCA, TA, PAN, MPA/GPA, CSS**
- **Visits every**
 - 3 months for 2 years then yearly
 - Every year

VCRC longitudinal study

	Boston University School of Medicine (VCRC)		Cleveland Clinic Foundation (VCRC)		Johns Hopkins University (VCRC)		Mayo Clinic (VCRC)		Mount Sinai Hospital, Toronto (VCRC)		St. Joseph's Hospital, Toronto (VCRC)		University of Pittsburgh (VCRC)		University of Utah (VCRC)		Total	
	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*	Cumulative	Current Year*
5502	19	0	12	0	18	2	45	4	11	2	72	25	1	1	3	3	181	37
5503	36	2	24	1	14	0	23	3	19	2	5	2	3	3	3	3	127	16
5504	14	2	6	0	8	0	7	1	12	2	17	1	1	1	1	1	66	8
5505	68	13	93	0	76	17	56	13	64	19	41	8	5	5	15	15	418	90
5506	28	2	14	1	25	4	13	2	32	8	10	2	0	0	2	2	124	21

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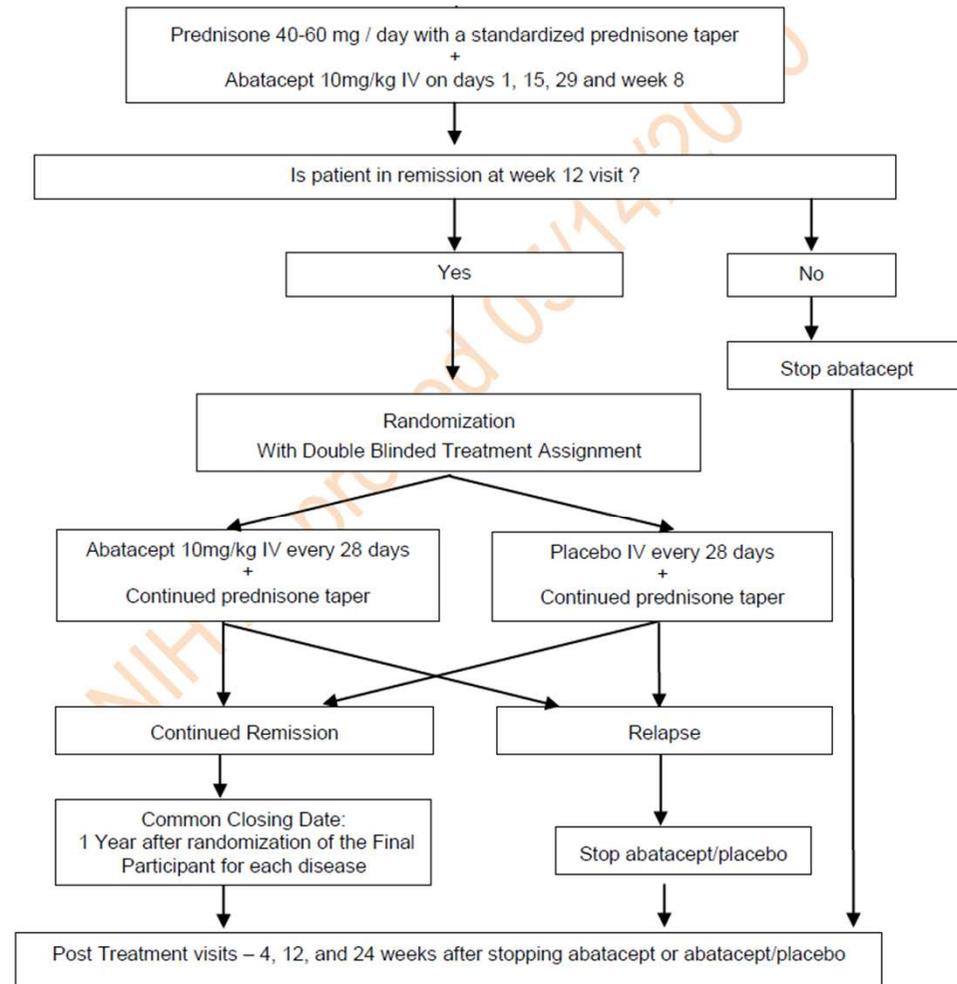
-  Branding
-  Grant

Protocol Management Tools

5502	VCRC Longitudinal Protocol for Giant Cell Arteritis
5503	VCRC Longitudinal Protocol for Takayasu's Arteritis
5504	VCRC Longitudinal Protocol for Polyarteritis Nodosa
5505	VCRC Longitudinal Protocol for Wegener's Granulomatosis and Micro...
5506	VCRC Longitudinal Protocol for Churg-Strauss Syndrome

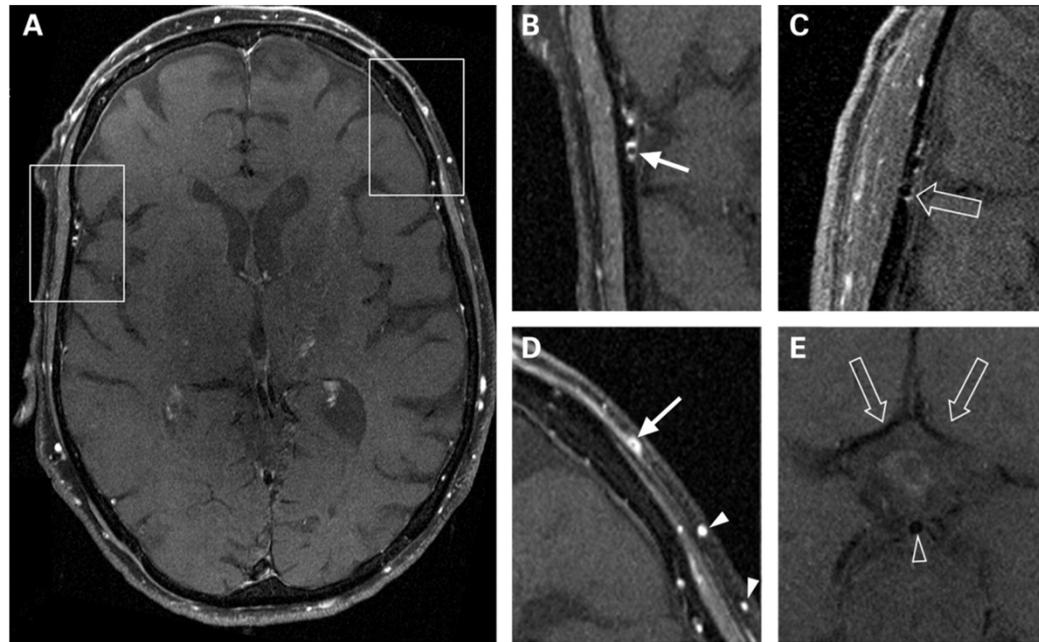
AGATA LVV

- VCRC 5523 (*and 5522 for GPA*)
- CTLA4-Ig
- 2 Hamilton
- 1 Toronto
- Total 39
- 33+33 Needed



McMaster's GCA / MRI study

- Dr. Khalidi
- Dr. Clements-Baker
- Dr. Rebello
- Dr. Ioannidis



Bley et al. Ann Rheum Dis 2009;68:1369-1370



PEXIVAS PEXIVAS PEXIVAS PEXIVAS PEXIVAS

PEXIVAS

a RCT of plasma exchange and
glucocorticoid dosing in ANCA
associated vasculitis

On behalf of the PEXIVAS Trial Group



Eligibility

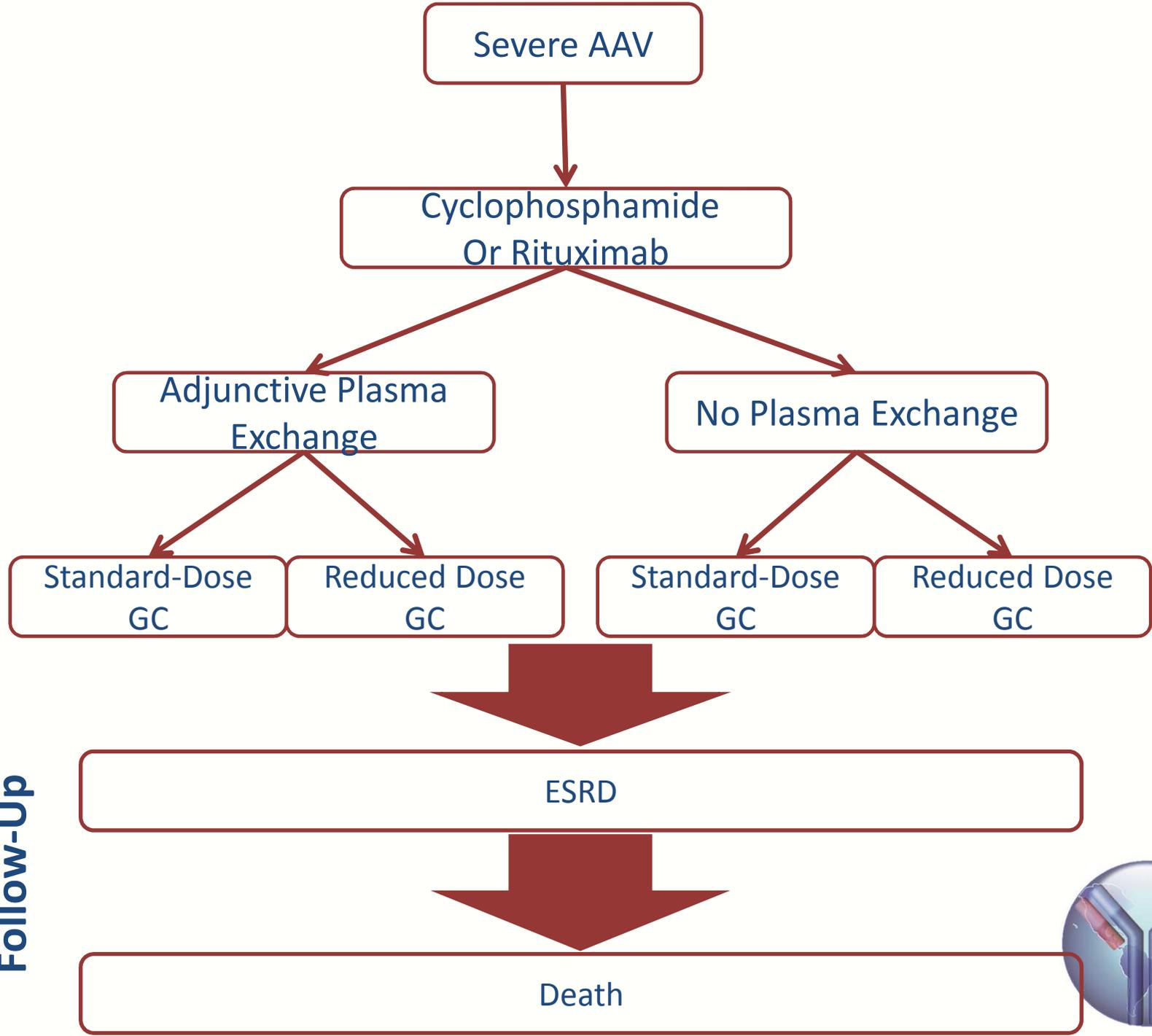
Inclusion

- New or Previously diagnosed GPA or MPA
- ANCA + (by ELISA)
- Current “severe” manifestation
 - GN with eGFR <50 ml/min
 - Lung hemorrhage
- Informed Consent or Deferred Consent

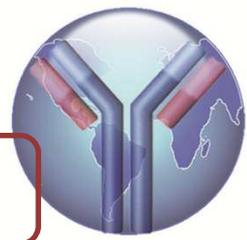
Exclusion

- <18 years old (<15 in peds centres)
- Concomitant anti-GBM or other non-AAV vasculitis
- Pregnant
- Received significant therapy for this presentation already
 - >1 IV dose or 2 weeks CYC
 - >1 dose RTX within 1 month
 - >14 days pred >30 mg/day
- Likely has ESRD already
- PLEX or other trial therapy mandated or contraindicated*





Follow-Up



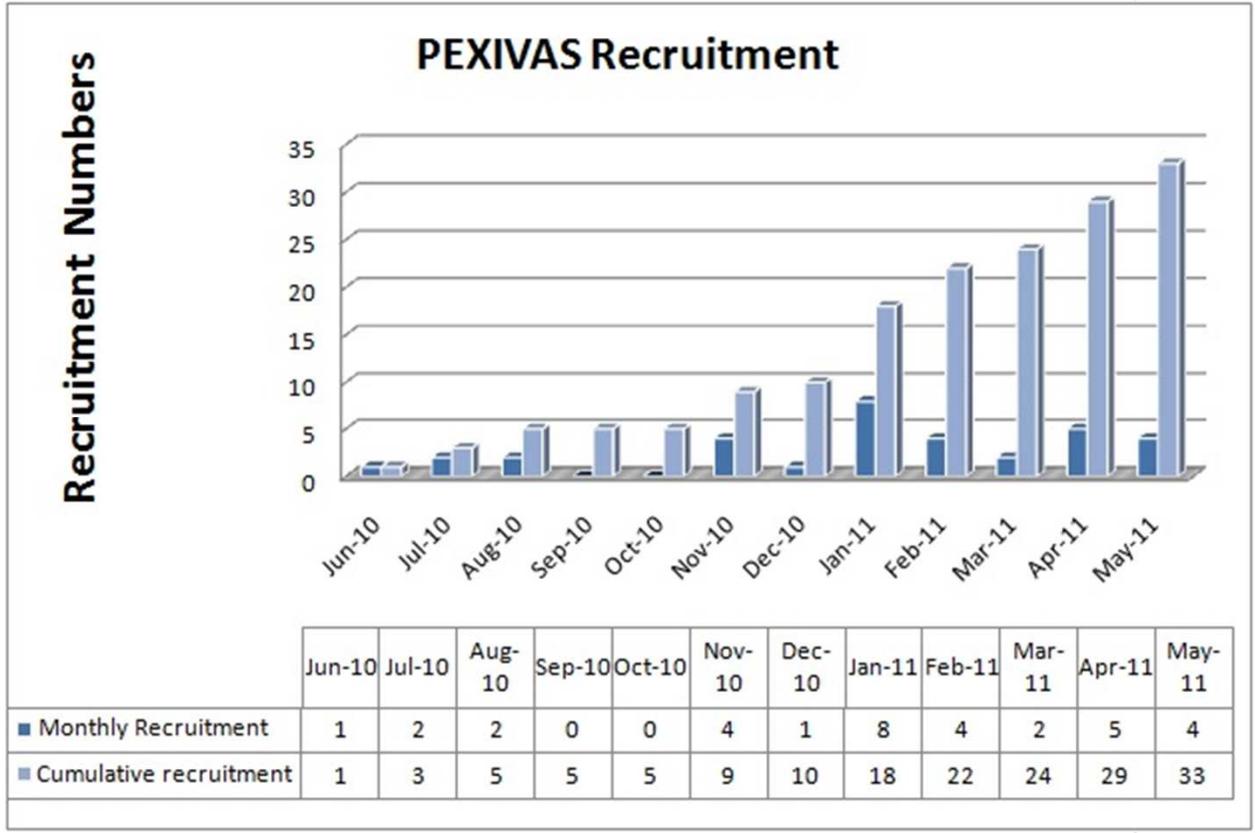
Study follow-up

- **Common study termination point**
- **Minimal follow-up = 2 years**
- **Recruitment over 5 years**
 - Maximal follow-up = 7 years

Outcomes

- Primary
 - Composite of ESRD or death
- Secondary
 - Sustained remission at 12 months
 - Adverse events
 - Health related quality of life
 - ESRD
 - Death





Canada (6 June 2011)
 2 from St Joseph's Hospital, Hamilton, Ontario, Canada
 2 from University of Alberta, Edmonton, Alberta, Canada

London, ON
 St Michael's, ON



VCRC Genetic Repository

One-Time DNA Protocol

- **VCRC 5510**
- **Aims**
 - Collect clinical data and DNA on patients with GCA, TA, PAN, GPA, MPA, CSS
 - Discover genetic markers that increase the risk of developing vasculitis
 - Discover genetic markers linked with certain symptoms of vasculitis
- **93/1,300 patients so far**

VCRC Genetic Repository

One-Time DNA Protocol

- **GWAS**
- **Candidate-gene studies and fine-scale genotyping**
- **2 x 10ml vials (purple top tubes)**
- **Sent to BU Genetics Lab. (code bar)**
- **Local REB approval**



Patients reported outcome studies / driven surveys

- **VCRC Reproductive Health in Men and Women with Vasculitis**

VCRC patient registry

<http://rarediseasesnetwork.epi.usf.edu/vcrc/index.htm>

RARE DISEASES CLINICAL RESEARCH NETWORK
Funded by the National Institutes of Health

RDCRN Home | View All Open Studies

VASCULITIS CLINICAL RESEARCH CONSORTIUM

Welcome! The Vasculitis Clinical Research Consortium (VCRC) is an integrated group of academic medical centers, patient support organizations, and clinical research resources dedicated to conducting clinical research in different forms of vasculitis. It is our goal to improve the care of patients with Wegener's granulomatosis, microscopic polyangiitis, Churg-Strauss syndrome, polyarteritis nodosa, Takayasu's arteritis, and giant cell (temporal) arteritis.

We Can Help You:

- Become aware of clinical research and clinical trial opportunities
- Connect with expert doctors
- Connect with patient support groups
- Get help in managing your disease

What Is The VCRC?

Information for Patients:

- Learn More
- Take Action
- Research Studies

Information for Physicians

Information for Investigators

News And Publications

Participating Clinical Centers

Contact Information

RDCRN RESEARCH MEMBERS LOGIN

Rare Diseases Media Center

INFORMATION FOR PATIENTS

LEARN MORE

Unsure of a condition or looking to learn more? Look below to find definitions and more helpful information.

- + Churg-Strauss Syndrome (CSS)
- + Giant Cell (Temporal) Arteritis (GCA)
- + Granulomatosis with Polyangiitis (Wegener's) (GPA)
- + Microscopic Polyangiitis (MPA)
- + Polyarteritis Nodosa (PAN)
- + Takayasu's Arteritis (TAK)

Useful Links

Glossary of Terms

Frequently Asked Questions

TAKE ACTION

Updated! [Find Information About Current Research Studies](#)

[How Can I Help? - Why your Participation Matters...](#)

Join the VCRC Contact Registry

Learn more about joining the VCRC Contact Registry

What is a Clinical Trial?

[Find Patient Support or Advocacy Groups](#)

INFORMATION FOR PHYSICIANS

Diseases defined...

Refer a Patient

Links and Resources

See also: Information for Investigators

New! Download the VCRC Contact Registry Paper Form

VCRC News and Publications

New England Vasculitis Foundation Health Care Provider Program

Saturday, March 19, 2011, 7 am to 11:15 am

Doubletree Guest Suites Hotel - Boston/Waltham

[View Full Announcement >](#)

Vasculitis Foundation New England Conference and Concert

> 2,000

Jennifer Harris

To: Jennifer Lloyd; Jennifer Lloyd
Subject: [TEST] Automation Email Special Message from the VCRC



Update



Visit us at: www.RareDiseasesNetwork.org/vasculitis

We have a brand new on-line research study open that might be of interest to you! Please read below for more information.

Dear Jennifer Schauble Lloyd

You are invited to participate in an on-line research study being conducted by the Vasculitis Clinical Research Consortium (VCRC) under the direction of Dr. Megan Clowse, from Duke University Medical Center and VCRC Investigators at the University of South Florida.

Purpose and Background

The purpose of this study is to learn about reproductive health, including fertility and pregnancies, in people with vasculitis.

Who Can Take This Survey?

Both men and women with vasculitis age 18 and older can participate in this study.

What This Study Involves

This study consists of an online survey. You will be asked to provide answers to a series of questions related to your reproductive health and vasculitis. The consent form explains the research study and your part in the study. If you decide to participate in this confidential research you will be directed to the survey after you read the consent form and choose that you would like to participate. The survey should take about 20-30 minutes of your time.

If you want to participate in this study, please [click here](#).

The Rare Diseases Clinical Research Network will make every effort to enroll all the patients we can, but we cannot make any guarantees that we will be able to enroll everyone in a particular study who wants to participate. Participation in research studies is voluntary. Deciding not to participate in a research study does not affect your ability to receive care at any of our Clinical Centers or from other physicians.

Stay Informed!

We want to keep you informed with the latest news and information. Keeping your contact information up to date can be done quickly and easily on the Web:

[Click Here to Update Your Information](#)

About the VCRC

The Vasculitis Clinical Research Consortium (VCRC) is an integrated group of academic medical centers, patient support organizations, and clinical research resources dedicated to conducting clinical research in different forms of vasculitis and improving the care of patients with vasculitis.

The Vasculitis Clinical Research Consortium is part of the National Institutes of Health's Rare Diseases Clinical Research Network. The VCRC continues to grow and is working on several new research projects concerning vasculitis. Check back with the VCRC website regularly for updates:

www.RareDiseasesNetwork.org/vasculitis

**467 responded
after 3 email
campaigns**

VCRC Reproductive Health in Men and Women with Vasculitis

- **Online questionnaire**

- 16 pages
- Electronic ICF

- **Aims**

- Compare infertility rate with or without CYC
- Compare pregnancy complication rate before vs after vasculitis onset

VCRC Reproductive Health Survey

Reproductive Health Survey

Thank you for volunteering to take part in this important survey.

There is a great need for patients and doctors to understand

- i) how having vasculitis and its treatment impact a patient's ability to have children;
- ii) how vasculitis in a pregnant woman affects the course of a pregnancy and the health of the newborn;
- iii) how pregnancy impacts vasculitis; and
- iv) other issues surrounding reproductive health for both women and men with vasculitis.

We ask women and men of all ages who have had vasculitis to complete the entire survey. The Vasculitis Clinical Research Consortium is conducting this research to collect data directly from patients to better understand many of these complex issues that are so vitally important to patients with vasculitis.

Please be aware that as you answer some of the questions, your screen may freeze and flicker for a few seconds as new information is displayed. This is normal for this program and is supposed to happen. If you need more time to complete the survey, you can save your answers and come back to the survey at another time. You will need to click submit at the end of the survey for your answers to be submitted.

Demographic Information

1. What is your age? _____ (years)
2. Please select the option that best describes your highest level of education.
 - Didn't go to school
 - Grade school (1-4 years)
 - Grade school (5-8 years)
 - Some high school (9-11 years)
 - High school diploma or GED
 - Vocational or training school
 - Some college or Associate Degree
 - College graduate or Baccalaureate Degree
 - Some post-graduate or professional
 - Master's Degree
 - Doctoral Degree (Ph.D., M.D., J.D., etc)
3. Which selection best describes your current marital status?
 - Married
 - Single
 - Separated
 - Divorced
 - Widowed
 - Not married, but in a committed relationship
4. Please indicate the best description of your race. You may select more than one option.
 - American Indian or Alaska Native
 - Asian
 - Black or African American
 - Native Hawaiian or Other Pacific Islander
 - White
 - Unknown or not reported
 - Prefer not to answer

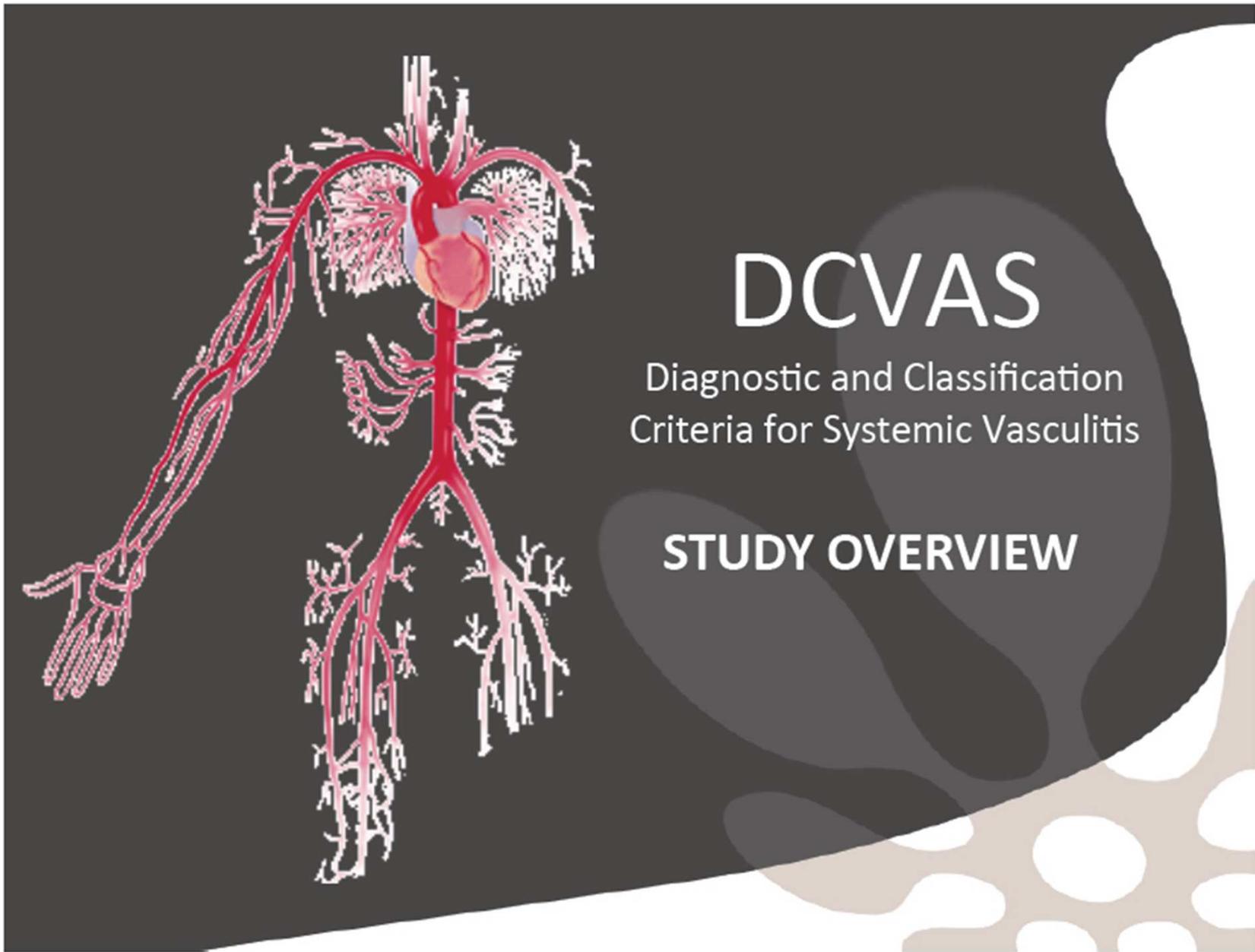
Patients driven survey / reported outcome studies

- **VCRC Reproductive Health in Men and Women with Vasculitis**
- **VCRC Pregnancy registry**
- **VCRC patient illness perception**
- **Edmonton study**

Trials and studies

- **Projects in Canada**

- Patients driven survey
- DCVAS
- CanVasc database/cohort
- Sherbrooke practice survey
- Canadian recommendations for diagnosis, management and follow-up



DCVAS

Diagnostic and Classification
Criteria for Systemic Vasculitis

STUDY OVERVIEW

DCVAS

- **Each center willing to participate to contact Rashid Luqmani**
dcvas@ndorms.ox.ac.uk
- **Each center will need local REB approval**
- **US \$15 per patients with full set of data (US \$10 if paper sheet)**

CanVasc database/cohort

- **2 options**
 - Paper record form to send to CanVasc
 - Locally stored Access® CanVasc database (duplicate → synchronizable)
- **Every center/MD can participate**
 - Local REB approval
 - Focus on CSS and Takayasu
- **Retrospective and prospective**

Important ongoing trials and studies outside Canada

- **VCRC AGATA GPA 5522**
- **CORTAGE**
- **CHUSPAN2**
- **REMAIN**
- **MYCYC**
- **MAINRITSAN**





(Possibly) important study projects outside Canada

- **Rituximab for maintenance (EUVAS)**
- **Gusperimus in AAV**
- **Mepolizumab in CSS**



(Possibly) important study projects outside Canada

- **Rituximab for maintenance**
- **Gusperimus**
- **Mepolizumab**

- **Apremilast**
- **Belimumab**
- **Anti-IL6 receptor**
- **Complement inhibitors**

Conclusions

- **Enroll patients in cohorts/studies/trials!!**
 - Rare diseases
 - New treatments
 - Drug cost coverage
- **Don't jump over the gun!**