

# Antibody screening for the SINAPPS2 treatment trial

## PPiP2 Study

Do you know a patient with symptoms of psychosis who might be willing to take part in research?

If so, please contact

[oxfordhealth.ppip@nhs.net](mailto:oxfordhealth.ppip@nhs.net)

### Why we need your help?

- Psychosis symptoms of 6-9% of patients with psychosis may be caused by pathogenic anti-neuronal membrane antibodies
- Affected patients may respond to immunotherapy and its efficacy and safety is being tested in SINAPPS2 treatment trial
- PPiP2 study sites **urgently** need to screen more than 4500 patients with psychosis to identify antibody-positive participants for SINAPPS2 trial

***SINAPPS2 is a double blinded placebo controlled randomised trial testing efficacy of IVIG/Rituximab for people with antibody associated psychosis***

### Who could be screened for anti-neuronal membrane antibodies?

Inclusion criteria	Exclusion criteria
Age 16-60	Any neurological disorder* Pregnancy
Acute psychotic symptom(s) lasting more than 2 weeks but no longer than 2 years in current episode (first episode of psychosis or relapse after at least 6 month of remission)	

\*Including multiple sclerosis, epilepsy, cerebrovascular disease, hydrocephalus, traumatic brain injury, meningo-encephalitis, systemic lupus erythematosus, CNS vasculitis.

### What will happen if your patient takes part?

- A blood sample will be taken and tested in Oxford for NMDAR, LGI1, GABA and CASPR2 antibodies (live assays).
- **Everyone asked to continue to take antipsychotic medication.**
- The local researcher will inform you about results in **7-10 days**
- Antibody-positive participants will be approached for SINAPPS2 trial



Contact [oxfordhealth.ppip@nhs.net](mailto:oxfordhealth.ppip@nhs.net)  
or visit [www.sinapps.org.uk](http://www.sinapps.org.uk)

# SINAPPS2 Trial:

## A Five Step Overview for Responsible Clinicians

### Identifying patients with antibody-associated psychosis through testing for antibodies in PPIp2

- Age 16 - 70
- Acute psychosis symptoms
- Anti-neuronal membrane antibody positive (NMDAR , LGI1, GABA-A and CASPR2 (Live assay))

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### Antibody test results

- Receiving test results via PPIp2 local team **within 7-10 days** and informing patients about results within 24-48 hours

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### Clinical referral of antibody positive patients to neurologist

- Responsible Clinician (RC) refers antibody positive patient to neurologists at SINAPPS2 site with part II summary or recent letter to GP and risk-assessment enclosed

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### Pre-screening contact with patient

- Referred patient approached by neurologist or SINAPPS2 researcher locally to explain the trial
- SINAPPS2 Participant Information Sheet provided
- Participants and their family members have opportunity to ask questions before the SINAPPS2 clinical screening visit is arranged

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### Screening visit at a SINAPPS2 site

- Written Informed consent
- Physician review and clinical assessments
- Blood tests (incl. Antibody assays)
- Final confirmation of eligibility for the trial and randomisation to IVIG/rituximab or placebo

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SINAPPS2



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- Baseline assessments
- Patient receives IVIG + Rituximab or placebo
- **Participants continue receiving mental health treatment as prescribed by their psychiatrist (e.g antipsychotic medication)**
- Monthly follow-up by phone and clinical visits over 12-18 months
- Unblinding after end of the trial (2024)