



## Australian Pregnancy Register for Women on Antiepileptic Medication

1800 069 722 | [www.apr.org.au](http://www.apr.org.au)

Principal Investigator: Prof Frank Vajda AO

Research Coordinators: Ms Janet Graham & Ms Alison Hitchcock

# Annual Report 2023

## Overview

The Australian Pregnancy Register (APR) is an independent project that has been running for 24 years nationally. We are an observational register and collect information about pregnant women with epilepsy, treated and untreated, to determine which AEDs are safest for the baby while protecting the mother from seizures.

As a result of this study, we are getting closer to defining safer treatment choices. This project has current ethics approval, overseen by Melbourne Health.

Potentially eligible women can enroll by:

1. Call: 1800 069 722
2. Email: [apr@mh.org.au](mailto:apr@mh.org.au)
3. Online: [www.apr.org.au](http://www.apr.org.au) Click on the “Register Now” button
4. Online through Epilepsy Action [www.epilepsy.org.au](http://www.epilepsy.org.au)-
5. Epilepsy & Pregnancy resources are also available

Health Care Professionals can assist with enrolment by making the first contact with the woman’s permission; this often enhances the chance of enrolment. The quickest way to assist is by completing the details through the “Register Now” button on either website.

Once enrolled, there are no appointments or visits for this study; all information is gathered by way of six telephone interviews (or a combination depending on point of enrolment)

1. On enrolment.
2. 7 months gestation.
3. 4-8 weeks post-delivery.
4. 1 year post-delivery.
5. At 5yrs of age (first year of primary school)
6. At 12yrs of age (first year of secondary school)

During the interviews, women have the opportunity to ask any question relevant to the pregnancy and birth, their epilepsy and their antiepileptic medication.

All care and treatment of participants remains with their GP or treating Specialists.



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### *Data Update*

Total Enquiries for Enrolment	3923 1 Nov 2022 – 31 Oct 2023 = 123
Total Enrolments	2899 1 Nov 2022 – 31 Oct 2023 = 83
Outcomes	2871 Includes 53 set of twins 48 lost to follow up by interview 3 declined to continue 6 birth defects identified
Total Live Births	2707
Live Births No Defects	2578 Includes 49 sets of twins + 3 x 1 of twin sets
Live Birth Defects	123 Includes 1 set of twins + 4 x 1 of twin sets
Live Birth Chromosome Defects	2
Live Birth Genetic abnormality	4
Total Abortions	95 1 set of twins spontaneous abort 1 set of twins induced for defects 1 x 1 of twin set
Still birth	18



**Australian  
Pregnancy  
Register  
(APR)**

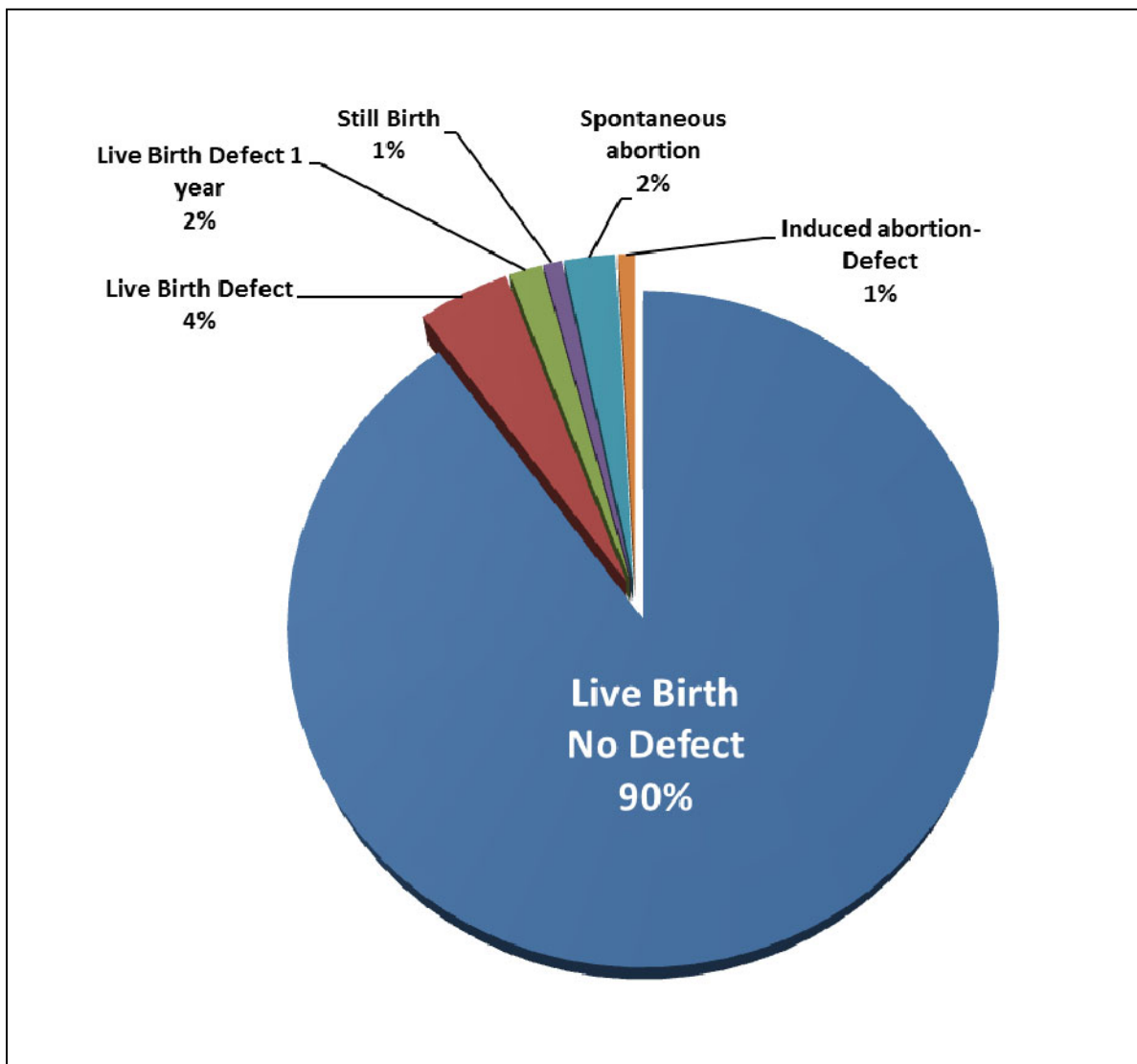
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### Outcomes





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### Enrolments by State

State	Total	2023
ACT	47	5
NSW	663	17
NT	18	0
QLD	663	22
SA	131	1
TAS	53	2
VIC	972	28
WA	306	8
<b>TOTAL</b>	<b>2853</b>	<b>83</b>



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### *Pharmacogenetics' sub study*

Continue to recruit families from the Pregnancy Register after the 4<sup>th</sup> interview.

Further collaborations with PGX- study continuing.

### *Neurobehavioral outcome study*

To compare the behavioural development of children who were exposed to antiepileptic medication during pregnancy to children who did not have this exposure.

To identify the impact on cognitive and behavioural development across the various stages of a child's development.

### *Lacosamide UCB*

Lacosamide Clearance sub-study - bloods and breast milk.

Continue to recruit.

2 participants completed.

### *EURAP*

Continue affiliation and participation in teleconferences and publications.

APR continues to provide data to enhance EURAP's numbers which have significant numbers for powered studies.



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### Academic Progress

#### Posters

The teratogenesis risk associated with pairs of antiseizure medications in women with epilepsy - ESA 2023

#### Presentations

The Teratogenesis risk associated with paired antiseizure medications in pregnant women with epilepsy - American Epilepsy Society 2022

#### Publications

- Specific fetal malformations following intrauterine exposure to antiseizure medication; Epub 2023 Apr 21. Frank Vajda<sup>1</sup>, Terence O'Brien<sup>2</sup>, Janet Graham<sup>3</sup>, Alison Hitchcock<sup>4</sup>, Piero Perucca<sup>5</sup>, Cecilie Lander<sup>6</sup>, Mervyn Eadie<sup>7</sup>.
- Changes over 24 years in a pregnancy register - teratogenicity and epileptic seizure control - Epilepsy and Behaviour; Manuscript Number: EB-D-23-00655.
- The teratogenesis risk associated with pairs of antiseizure medications in women with epilepsy - Epilepsy Research.
- Risk of major congenital malformations with exposure to antiseizure medications: an update from the EURAP registry; Presented at Dublin Congress Sep 2023.
- An economic evaluation of the community benefit of the Australian Pregnancy Register of anti-seizure medication; Epub 2022 Dec 2. 2023 Mar 7; 100(10):e1028-e1037. doi: 10.1212/WNL.0000000000201655. Zanfina Ademi, Clara Marquina, Piero Perucca, Alison Hitchcock, Janet Graham, Danny Liew, Terence J. O'Brien, and Frank Vajda. Neurology.
- Proposal for reference values for the developmental effects of valproate based on human data using a benchmark dose approach. *Regul Toxicol Pharmacol.* 2023 Mar; 139:105367. doi: 10.1016/j.yrtph.2023.105367. Epub 2023 Feb 22. Manière-Guerrero I, Bonizzoni E, Battino D, Clinard F, Mathieu-Huart A, Perucca E, Pouzaud F, Tomson T, Thomas SV, Vajda F, Rousselle C.



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### *Sponsors*

#### **Main Sponsor**

Epilepsy Action Australia

#### **Additional Sponsors**

UCB Pharma

Eisai

The Epilepsy Society of Australia

The Royal Melbourne Hospital Neuroscience Foundation

Sponsors are acknowledged on all academic posters and presentations.

APR is extremely grateful for the on-going support of our sponsors, who provide 100% of the project funding and without whom this research could not continue.

### *Research Team*

#### **Director & Principal Investigator**

Prof Frank Vajda AO

#### **Principal Investigator**

Prof Cecilie Lander AM

#### **Co-Investigator**

Prof Terry O'Brien

#### **Research Coordinators**

Janet Graham

Alison Hitchcock

#### **Treasurer**

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