APON Interest Group	Clinical trials and registries		
Webinar 1 date	21 February 2020		
In attendance	Heidi	Nicholl	Emerge Australia
	Jess	Kauhausen	Emerge Australia
	Simonne	Neil	Maddie Riewoldt's Vision
	Laura	Birks	MND Australia
	Toni	Catton	Mito Foundation
	Chris	Walker	Parenteral Nutrition Down Under Inc.
	Megan	Donnell	Sanfilippo Children's Foundation
	Kristina	Elvidge	Sanfilippo Children's Foundation
	Meredith	Cummins	NeuroEndocrine Cancer Australia
	Klair	Bayley	Save Our Sons Duchenne Foundation
	Marlene	Squance	Autoimmune Resource & Research Centre
Apologies	Nettie	Burke	Cystic Fibrosis Australia
	Melanie	Funk	Hands to Hold Ltd
	Hayley	Lethlean	Muscular Dystrophy WA
	Hannah	Heather	Pink Hope
	Christine	Cockburn	Rare Cancers Australia
	Caroline	Zoers	Australasian College of Dermatologists
Facilitator	Nicola Straiton, Australian Clinical Trials Alliance		
Observer(s)	Catherine Holliday, Centre for Community-Driven Research		

Introduction and purpose	This interest group will think about different approaches to community-based clinical registries and see where there are opportunities for collaboration, leveraging existing data collection mechanisms, information sharing and how clinical registries are used to track uptake and interest in clinical trials. (Note: This may also be an area of work in collaboration with My Health Record/Australian Digital Health Agency) In relation to clinical trials, the group will discuss what a national, community-driven approach might be to increasing awareness of clinical trials. How do we encourage both patients and clinicians to open up more conversations about clinical trials, so that is becomes a regular part of treatment discussions? There will be three interest group meetings that will be designed to build momentum towards the APON 2020 annual meeting in Melbourne (15-16 June). At the APON conference, we will draw on all of the work derived from the previous meetings and members will work with a pro-bono advertising/PR company to develop a national campaign to raise awareness of clinical trials (as an important part of treatment discussions). This could potentially then be developed into a recommendation to government.
Consultation question 1	The facilitator explained that this first meeting of the interest group will have a clinical registry focus and the next one will focus on clinical trials. Participants will be asked if any patient organisations are involved in clinical registries and for those

	group, ask what they have done, any recommendations and whether they feel the results have been worth the effort. Participants will also be asked about other data collection initiatives that with some additional input, could be extended to reflect a clinical registry.
APON member feedback	There were a number of organisations that had been involved in clinical registries at various levels, and across various models including clinician-led registries and patient-led registries. Common challenges with clinician-led registries were that, as it relies on clinicians to curate the data, it is difficult as they are time-poor already. It was noted that there can be concerns from clinicians (with patient-led registries) with what is happening with the data if they are not the ones controlling it. There were variations in the clinician-led model with some being largely hospital-based and others being a collaborative model between academic and public health units or hospitals. “Clinicians don't like inputting data especially if they're not paid to do it or have time to do it. Patient led registries, you have to have a driven community that are willing to spend the time and if they don't see the value in the data and then not getting feedback, then it's going to fail and that's something that we learnt. The summit would work, if some are patient led registry would be the perfect solution, but for us that it just wasn't.” “That really if you don't incentivize that and clinicians are so busy anyway, they fit so much in their day that if you're not incentivizing it or if they're not actually involved in any of the research that's coming out of it, you're really asking them to go well above and beyond what they do. It's from that point of view, I do understand that has been one of the obstacles to actually ensuring that we capture every patient with a plastic and then you're in Australia.” Common challenges with patient-led registries was primarily maintaining data integrity. It was noted however that this model had worked well in the USA, just not in Australia. Gaining local ethics was a challenge with any model of registry. There were organisations present that had significant experience in registries and as evident by the discussion, it is not one-size-fits-all: “We've got experience in every single model we feel, and it doesn't work for everybody and I think that's really important. There isn't a 'one-stop' shop for these things, so I'll be keen to hear what others too. We've certainly found this new model the clinicians love it. It's a way that we've managed to engage with the adult clinicians as well because Duchenne, our area was very pediatric driven. Now we've been able to get the adult clinicians involved. Yes, that's my experience.” The challenge of funding registries was discussed, and the significant contribution of patient organisations in supporting registries was noted: “Having said that, the registries at times run on the smell of an oily rag. I do feel…that if we weren't actually providing funding for it would be very difficult for it to continue in its current capacity. I'm sure it will continue in some way, but without the not-for-profit support, it really would not have the capacity to really achieve what it's trying to do. I do feel that our support has been very instrumental and very

	important. It's doing incredible work." The amount of work that goes into a successful registry was evident. APON members spoke about it not just being a case of someone entering data, but also guiding patients to be involved. There were some really interesting examples of patient organisations driving innovation in this space and also, making sure various platforms can be leveraged (or example, NeuroEndocrine Cancer Australia spoke about clinical registries being available on apps and then used for clinical trial alerts. It was noted that there were some technology barriers to this, but these were able to be overcome: "Some of the patients have bricks of phones, they weren't able to actually go into an app store, but we fine-tuned that. We're now rolling it out to the other sites where we have a volunteer that's available on the day that they given their half or one of the nurse coordinators and we can get the patients to load it all up on at the time and then they can start some entering their data." Other models that were described were leveraging biobanks with annotated clinical data and linking in with international registries. In one case described, the Australian arm was supported by industry. However, there were issues noted when the international component of a registry stops recruitment and the impact on the other arms of the registry: "Then, now what we've found is now that the international database has stopped recruitment and there's no more money coming in, there's no more recruitment into the Australian database because the nurses and the clinicians are not getting paid for their time to put the data in. That's the richness and the fallback of a database is you need to have money behind it to keep the information generated." There were some organisations that could see potential in the Patient Pathways telehealth nurse program being used as a form of clinical registry, as so much rich information is already being collected. "We're using our Telehealth Nurse questionnaire from CCDR. It's not exactly the same thing, but because we're on the Telehealth Nurse Pilot Pathways program, then we've already mapped out to some extent a bit of a data dictionary of what would go in. It's not 100% and there might be differences, but that's been really helpful." There were comments made by some organisations about the importance of communication, that is, making it clear what the purpose of the registry is, and also, involving the community in the design of the registry" "They want to understand the purpose. They want to know that their data is safe and what it's going to be used for. Our community specifically, it was a very big thing getting ethics ensuring that there was no coercion in providing that information that you're not promising clinical trial opportunities, but that is one of the, obviously, the mission, that cope with the registry. Up-to-date information, finding a way to engage and keep families informed of what the registry is being used for, that's something very new that's happening with our new website we'll be launching." "I know with our app, when it was being planned for the patients, we put it through our Consumer Advisory Group. Once we got to see if he's asking the right questions

	and is it going to meet their need, so that was a big, very important task of the app.”
Consultation question 2	The facilitator asked what purpose clinical registries were used for? That is, why is data being collected
APON member feedback	The main reasons described were: • To understand the patient population and to be able to go to government to advocate. • For clinical trials, to get industry to bring clinical trials to Australia and access to clinical trials.
Observations and action items for CCDR	CCDR provided some observations and next steps from the conversations held in the webinar. **Observation 1: It is clear that there are a number of different models that have been tried and tested, with various levels of success.** **Action item 1:** CCDR will take a look to see if anything is happening at a federal level to see if there are any initiatives that look at optimum clinical registry structure what's been funded in the past three years through on a federal level. Following that, we can do a round of structured interviews just to capture the expertise in the group and what has been shared today in more of a formal way to understand different approaches, what's worked and what hasn't from a patient organisation perspective. We will collected this systematically so that we can compile it in a stringent way. Through this, we will also aim to capture new innovative approaches, and how existing platforms have been leveraged to support clinical trials for example.