

Infrastructure Needs for Research on Pregnancy and Lactation and Pediatrics: Current Status

Infrastructure Need	Measure	Pregnancy and Lactation	Pediatrics
Workforce – Current (FY 2017) NIH PIs	NIH PIs in relevant research categories ¹	783	8,444
	NIH PIs with projects related to pharmacology within relevant research categories	79	967
	NIH PIs in relevant research categories with appointment (joint or single) in pharmacology-related departments OR with a PharmD degree	12	162
Workforce – Recent (2013-2017) NIH training and career development awardees	K12 scholars with pharmacology background or research, 2012-2017	2	~24 (estimated)
	Individual K awardees with pharmacology related projects, FY 2017	4	~31 (estimated)
	T32 pharmacology programs with specialty focus	2	11
	T32 postdoc trainees from pharmacology programs with specialty focus	4	60
	T32 postdoc trainees with pharmacology background	62	
Clinical Research Networks	NIH Clinical Research Networks with specialty focus, and their funding levels	OPRC: \$2.6 M MFMU: \$16.8 M GN: \$6.4 M	~53 pediatric clinical networks (estimated)
	Number of ongoing open CT.gov registered studies related to pharmacological therapies within these networks, 2017 ²	OPRC: 9 MFMU: 4 GN: 2	~221 (estimated)
Inclusion of Population	Policies or requirements for inclusion of target population	No policies or requirements	NIH policy requires inclusion, with allowed exceptions
	Percent of phase III NIH funded open clinical trials including relevant population, 2017	12	29
Industry involvement	Incentives available to industry	None	Additional exclusivity period available under BPCA
	Liability concerns	Often cited as a barrier to research	Often cited as a barrier to research
	FDA procedures and requirements	No pregnancy or lactation data required	BPCA and PREA may require some pediatric data

¹ For pregnancy and lactation, relevant NIH categories include Pregnancy; Breastfeeding, Lactation and Breast Milk; and Maternal Health. For pediatrics, the NIH Pediatrics category was used.

² Note: not all network studies are related to the use of therapies in pregnancy and lactation; some observational studies, for example, are focused on identifying risk factors for certain conditions.