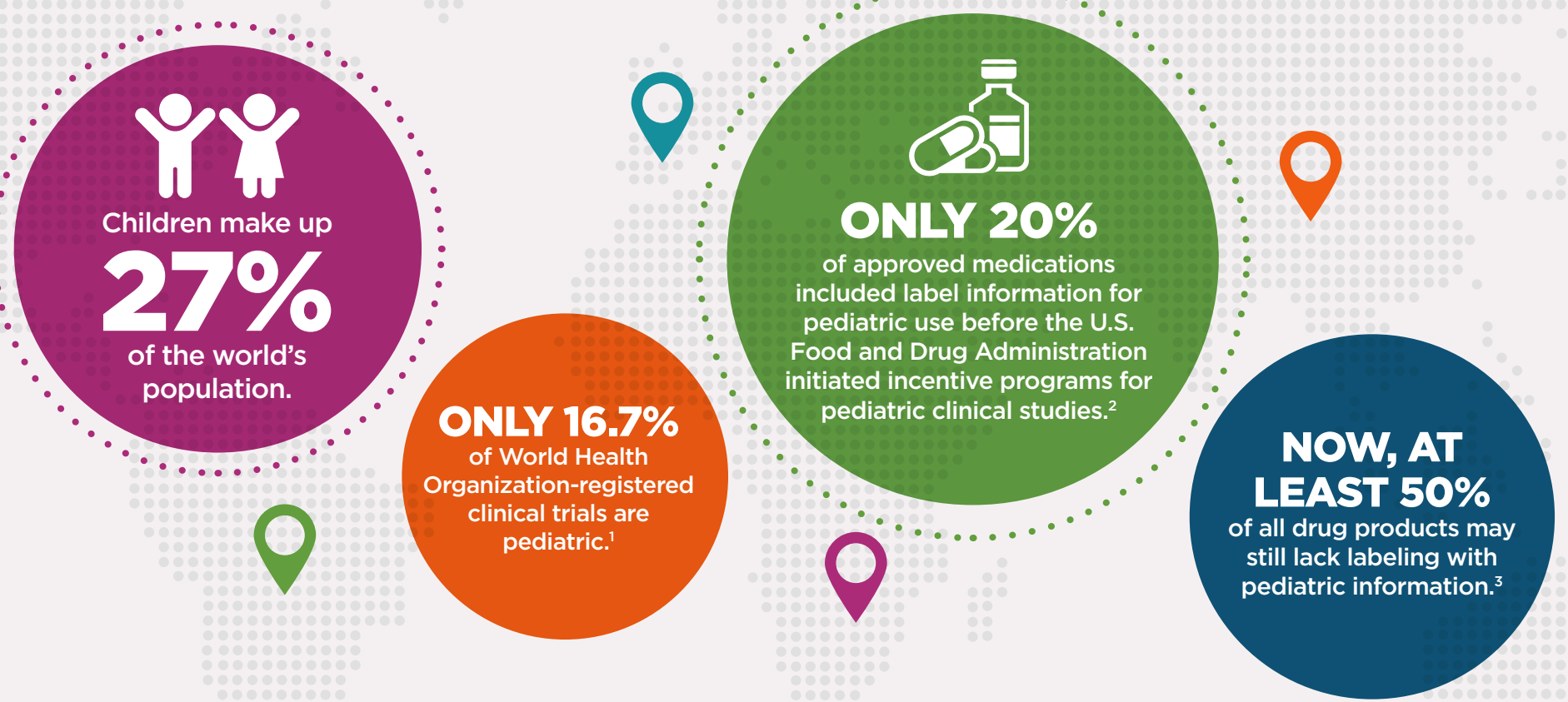


OVERCOMING THE CHALLENGES OF PEDIATRIC CLINICAL RESEARCH

Children are severely underrepresented in the world of clinical research.



This is bad news for kids, even though they have long relied on and often benefitted from off-label use of the vast majority of drugs prescribed to them.



Drugs without proper clinical research in pediatric patients greatly raises the risk of unexpected adverse events, suboptimal therapy, and inappropriate dosing.⁴

211,209 visits to the emergency room were by children 12 or younger due to adverse drug reactions in 2008 alone.⁵

FDA incentive programs have removed some of the hurdles to completing these critical pediatric trials.



Companies can receive 6 extra months of marketing exclusivity for completing pediatric studies requested by the FDA.⁵



The FDA granted marketing exclusivity to 189 drug sponsors extending studies to children from 1998-2012.



57% of the 189 drugs granted exclusivity received new or expanded pediatric indications, and **92%** received new pediatric labeling information.⁶



The Foundation for the National Institutes of Health offers some trial funding for the study of off-patent drugs in children.⁷

To Design an Effective Pediatric Clinical Trial, You Must Consider:



MAKE YOUR PEDIATRIC CLINICAL RESEARCH A SUCCESS WITH WORLDWIDE CLINICAL TRIALS

Our experts offer uncommon support in the clinical, technical, and regulatory requirements underpinning pediatric clinical development programs. Our successes in rare diseases, study site development, and operational agility can transform the experience for our clients and the families involved in our studies. Find out how we turn our expertise and unflagging devotion to quality into seamless, effective pediatric research programs. Learn more about **Worldwide's uncommon commitment to pediatric clinical trial solutions.**

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