ReGRoW Pilot: Repurposing Grants for the Rest of World

Providing repurposing research grants to clinicians and researchers in low and low-middle income countries to build capacity for research <u>from within</u> the developing world and to find treatments <u>for</u> the developing world

OVERVIEW: WHY ReGRoW?

Need

- **The NEED for scientific capacity building and access to medicines is HIGHEST in developing countries,** but global R&D investment is focused primarily in the US, Europe, China and Japan
- The 10/90 Gap: Only 5-10% of all global health research is directed to research on health problems that affect 90% of the world's population, and only a small portion of this funding actually goes to researchers in developing countries

Opportunity

Provide repurposing research grants to clinicians and researchers in developing countries to:

- **Build capacity for research FROM WITHIN the developing world FOR the developing world**
- Local problems are best solved locally
- Support retention of scientific talent within developing countries
- **Repurposing drives more treatments to more patients more quickly for unsolved diseases**: cost of repurposing clinical trials is significantly lower than traditional clinical trials (10 – 20x less)

ELIGIBILITY FOR PILOT

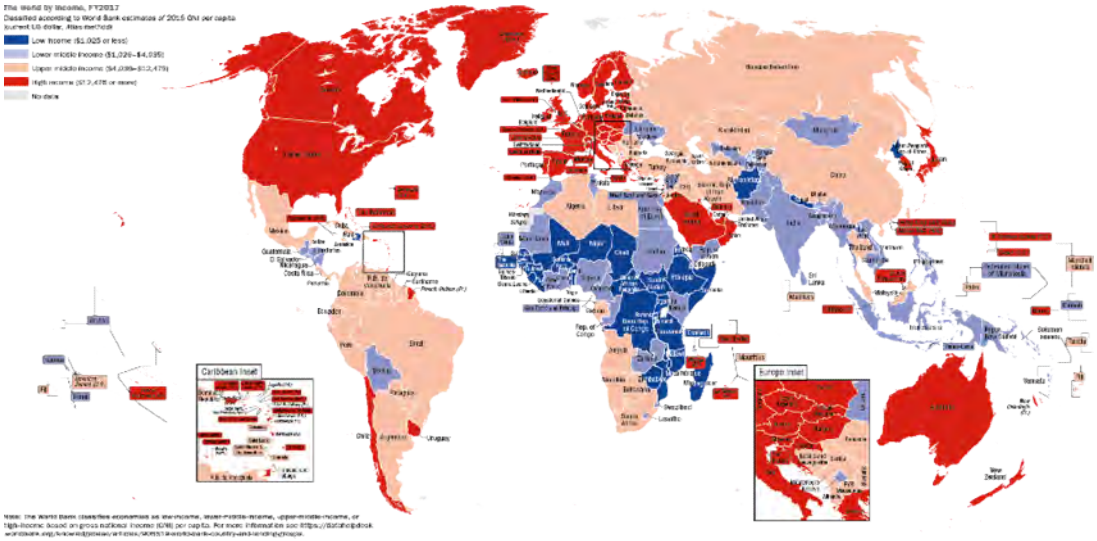
Eligible projects will:

- Serve an unmet medical need in any disease area – ReGRoW is disease-agnostic
- Use only generic or off-patent drugs or drug-like compounds (including nutraceuticals and indigenous medicines), with current access to the therapy in-country
- Be human / clinical research projects only
- Be in English with budget submission in US$; optional video submission
- Submit using CureAccelerator platform

Eligible research institutions will be "Research Ready":

- **Institutions based in low and lower-middle income countries** (per the World Bank – see image below)
- Have received previous external, 3rd party clinical research funding (government, NGO, private foundation or private sources)
- Have an IRB system or equivalent in place
- Follow WHO's GLC, GCLP and/or GCP guidelines or equivalent
- Have past or current experience with human / clinical research

Approved grants will range from US$25,000 – US$50,000. Initial submission is a high level proposal only; selected proposals are invited to submit a full grant application.



ReGRoW Pilot:
Repurposing Grants for the Rest of World

NEXT STEPS:

1. Outreach to NGOs for best practices and connecting to eligible institutions / researchers
2. Raise $250,000 to fund the ReGRoW Pilot, including 3 initial grants of roughly $50,000 each

DETAILS OF PILOT PLANNING TO DATE

Before Funding Opportunity RFP Launch

- Recruitment of proposal reviewers
- Adapting CureAccelerator Proposal Form for ReGRoW submissions
- Proactive outreach to eligible institutions through NGOs, global health policy university contacts

Goals for Phase 1 of Pilot

- Engagement of and partnership with NFPs, NGOs, initiatives and other Access to Medicine efforts already in play
- Build a committee / pool of scientific reviewers for proposal submissions
- Launch RFP and collect proposal submissions
- Develop plan / processes for Phase 2 of Pilot
- Develop a plan / research success metrics for Phase 2 of Pilot

Measuring Success of Phase 1 of Pilot

- Number of in-country research institutions, health systems, NGOs, etc. engaged
- Number of proposal submissions received; number of proposal submissions selected for scoring

Not In Scope of Pilot

- Therapies still under patent or exclusivity anywhere
- Devices and diagnostics
- Pre-clinical / animal and retrospective studies
- Researchers / institutions in upper middle income countries

CURRENT TIMELINE

1st Half 2019
- Finalize pilot planning and funding opportunity RFP
- Stakeholder outreach; CUGH conference
- Continue fundraising for Pilot

2nd Half 2019
- Launch and promote funding opportunity
- Recruit reviewers

Early 2020
- Funding opportunity RFP Deadline
- Review and prioritize proposal submissions
- Select those ranked for full grant applications

Mid to Late 2020
- Review grant applications and select grant recipients
- Administer and manage funded grants

Post Phase 2 Goals for Future Conversation

- Aim of future grants: Research outcomes vs capacity building
- Development of in-country clinical trial offices
- Capacity-building researcher training
- Mentorship program with upper income country researchers

Part of Phase 2 of Pilot

- Anything downstream from research grant approval
- Success measures specifics related to research results of Phases 1 and 2 of pilot
- Detailed procedures and logistics for research grant management, such as research timeline delays, post-research patient outreach, etc.

WHAT IS REPURPOSING?

Medical repurposing tests drugs, nutraceuticals and other products that already have regulatory approval and are readily available to determine safety and efficacy in treating another indication.

CuresWithinReach

CUREACCELERATOR®

ReGRoW Pilot Program:
Repurposing Grants for the Rest of World

NOT-FOR-PROFIT LEAD: CURES WITHIN REACH

- Cures Within Reach (CWR) is a neutral, not-for-profit partner to all medical research stakeholders and is a disease agnostic thought-leader in repurposing clinical research, since 2005
- **Mission: Improve patient quality and length of life by leveraging the unrealized clinical potential and missed therapeutic opportunities in existing medicine and science**
    - Leverage the speed, safety and cost-effectiveness of medical repurposing research, **driving more treatments to more patients more quickly**, by clinically testing approved drugs, devices, nutraceuticals and other products for any unsolved disease indication

Cures Within Reach Is the Ideal Lead for this Initiative

- CWR can build on our current successes to expand the global impact of repurposing, helping more of the 350 million patients worldwide who suffer from an unsolved disease, regardless of where they live
- CWR stakeholders are motivated by clinical infrastructure and capacity-building goals, sustainable models and patient-centric partnerships that improve health and quality of life
- CWR is uniquely qualified to be both the **value-driving facilitator** of conversation and action among interested stakeholders to create impact in global health through repurposing, and the **value-driving catalyst** of clinical repurposing research in developing countries through our CureAccelerator platform

CureAccelerator

- This platform, launched in 2015, has proven successful in receiving and prioritizing funding opportunity Requests for Proposals and submissions of repurposing research proposals from the US, Canada and Europe, with subsequent research agreements executed

OVERVIEW: PARTICIPANTS TO DATE

Since January 2018, stakeholders representing pharma industry, global health policy, pharma services, NGOs, philanthropy and other organizations have participated in planning-to-date

- Pharma Industry: Led by Takeda, plus Horizon Pharma, Pfizer, AbbVie, Abbott, Paragon Biosciences
- Global Health Policy: Northwestern University, University of Chicago, University of Illinois at Chicago
- Pharma Services: Vetter Pharma, ZS Associates, FHI 360
- Others: CHAI, Advocate Health, Kinship Foundation (Searle Funds at The Chicago Community Trust)

CuresWithinReach

For more info: email barbara@cureswithinreach.org, call 1.847.745.1246 or visit cureswithinreach.org

CUREACCELERATOR®