Advancing Research Discovery and Drug Development while Reducing Investment Risk

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Martin A. Dueñas
Director, Health Research Management Practice

A Global Public–Private Partnership
https://onpar.leidosweb.com/
Vision: To support the research ecosystem to advance medicines to patients faster
Information flow

- You went to get the information
- One place only
- Limited

- Information comes to you
- Global
- Unlimited
OnPAR with Dimensions: Solutions

Timeline

Altmetric: Social Media

Global Ideas
Global Unfunded
Global Funded

Research Grant Applications or Ideas

Time
< 4-5 year  < 2-4 years  < 2 years

Publications
Patents
Clinical Trials

Providing research information 2-5 years ahead of current practices to de-risk R&D

X = only available through OnPAR with Dimensions – not in the public domain
OnPAR: Executive Summary

Access to global high-quality, unfunded, biomedical research applications

Future goals:
- Pre-peer-review research ideas
- Assets from pharma
- Assets from tech transfer offices
- Expansion to include energy, CMS, social science, NASA, and agricultural research applications

Co-funding opportunities with members
- Foundations, pharmaceuticals, venture capitals, and others

Marketing and communication

https://onpar.leidosweb.com/

Dimensions

Funding database of >2.5M projects/awards
Access to >26M publications
Web-based metrics (altmetric) that track online activity
Additional data available:
- Patents
- Clinical trials
- FDA drugs
- Policy documents

Lowering research investment risk
- Information sharing, facilitating collaborations, and avoiding duplication of effort

Accelerating research discovery and scientific advances

Please contact: duenasm@leidos.com
85-90% of high-quality, grant research applications are unfunded

Funding by the NIH declined by 22% between 2003 and 2015

(1) https://www.wsj.com/articles/the-breakdown-in-biomedical-research-1491576749
The Solution

**OnPAR**

Online Partnership to Accelerate Research

A new funding model that advances research discovery and drug development while lowering investment risk
A Global Public–Private Partnership

A matchmaking platform…

OnPAR Goal: The goal of the Online Partnership to Accelerate Research is to match quality biomedical research unfunded applications with priority areas of interest of private biomedical foundations, pharmaceutical and biotechnology companies, venture capital funds, and other private funds.

OnPAR: https://onpar.leidosweb.com/
OnPAR has grown from a simple concept of optimizing high-quality, unfunded NIH applications to a ONE-STOP knowledge source to accelerate research discovery and drug development and enhance investment decision making.
A Knowledge Database to Lower Investment Risk and Accelerate Research

Quasi-Publicly Available Data = Innovation Gap #1

Previously Unavailable Data = Innovation Gap #2
OnPAR: Summary

- Matchmaking platform providing access to highly-scored global unfunded applications
- Ability to sustain potential new and innovative projects
- Ability to support new and young investigators
- Potential co-funding opportunities with other government and non-government organizations
- Potential to create a new innovative program that might have a key research impact, plus a great marketing and development opportunity
- Extensive global research knowledge to inform R&D investment decisions
- Expand your global outreach
OnPAR Pillars

A Global Collaborative Effort
OnPAR is a private business venture that will provide access to a global pipeline of innovative, unpublished research projects that can either supplement internal projects or provide innovative new ideas for future medical products.

Potential Partners [Government Funding Agencies]: NIH, Japan Agency for Medical Research and Development, Canada Institute of Health Research, EU Horizon 2020, United Kingdom Medical Research Council & National Institute for Health Research, Australia National Health Medical Research Council, Brazil Fundação Oswaldo Cruz, and others.

Applicants:
- Submit same applications submitted to Government agency
- No cost

Members [Funders]:
- Non-Profit: Private biomedical foundations and private funders
- For Profit: Pharmaceuticals, biotechs, venture capitals, others
Partners

Current/Future:

- National Institutes of Health (NIH) is a founding partner.
- Leidos is in conversation with many organizations to join OnPAR as Partners in 2016.
- Going forward, Leidos will continue to reach out to other organizations worldwide.
- Leidos is in conversation with other sectors to expand OnPAR focus areas, i.e., Department of Energy, NASA, USDA, and others.

Benefits:

- Potential funding for unfunded applicants.
- Potential co-funding with OnPAR members.
- Accelerated research discoveries that impact public health.
Partners: Global Pipeline

National Science Foundation

European Commission

HORIZON 2020

Biomedical Advanced Research and Development Authority (BARDA)

Instituto de Salud Carlos III

Medical Research Council

Centers for Disease Control and Prevention

National Institute for Health Research

Australian Government

Japanese Agency for Medical Research and Development

Canadian Institutes of Health Research

Leidos Proprietary
Applicants

Current/Future:

► U.S. research investigators that have applied to NIH
► Future: Global research investigators that have applied to all partner organizations

Benefits:

► Funding for unfunded Government applications
► No cost to apply
► No need to develop a new application — PIs must submit the same application that was submitted to the Government funding agency (along with the peer review summary statement)
► [Future] Access to “failed” pre- and clinical drugs information from pharmaceutical companies that can potentially impact research
Members

Current/Future:

► Several U.S. foundations
► Future: In conversation with +400 global foundations, pharmaceutical companies, venture capital funders, and other private funders

Benefits:

► Access to fully peer-reviewed applications, U.S. and international
► [Future] Access to “failed” pre- and clinical drug information from pharmaceutical companies that can potentially impact research
► [Future] Access to “ready-for-commercialization” assets
Members: Additional Benefits

- Customized OnPAR portal
  - Global unfunded applicants start uploading abstracts from fellowships and basic research grants through translational topics and Phase I/II clinical research
  - View of the top 25 funded and published projects related to unfunded application

- Co-authoring an editorial to submit to a journal, if applicable

- Marketing and outreach
  - Conferences and seminars
  - Universities and medical centers
  - Biotechnology companies
  - Others

- International applications
  - OnPAR website is available in 8 languages

- Potential co-funding opportunities
  - With Government agencies, foundations, pharmaceuticals, or other organizations

- Ideas of what other members are doing for marketing, communication, and fundraising efforts around OnPAR

- Dimensions database (UberResearch), if applicable
  - Access to over 2.5 million funded projects and more than 26 million publications
  - Understanding of the global landscape of your research priority areas and related disease
Members

- Adenoid Cystic Carcinoma Research Foundation
- Breast Cancer Research Foundation
- Children’s Tumor Foundation
- EB Research Partnership
- Epilepsy Foundation
- JDRF
- National Alopecia Areata Foundation
- Parent Project Muscular Dystrophy
- Cystinosis Research Foundation - New
- HealthfundIT - New
- Daiichi Sankyo – New
- Cure Alzheimer’s Fund - New
Future OnPAR Projects

- Submission/review of “ideas” – prior to peer-review
- Direct requests for proposals (RFPs) through OnPAR
- Partners’ and funders’ RFPs (Innovative Medicine Initiative-like)
- Access to pre-clinical and Phase I/II/III failed drug compounds from pharma/biotech
- Access to NIH and global academic centers “ready for commercialization” pipeline
- Expansion into other programs, i.e., Department of Energy, NASA, Department of Agriculture
So What: Global Solution to Research Discovery and Product Development

Internal Data
- Clinical Data
- Assay Data
- Structural Data
- Genetic Data
- Pathway Data
- Models
- Additional Internal DBs

De-risk & Accelerate Path

External Data
- Ideas
- Unfunded
- Funded
- Patents
- Publications
- Additional External DBs

OnPAR Global Data

Future
- "Failed" pre- and clinical drug candidates from pharmaceuticals
- Ready for commercialization projects from:
  - NIH
  - Academic Centers
Current Challenges in the Research Ecosystem

- Agencies working on the same disease/problem have no standard data formats
- Sharing data, resources, and knowledge has not been fostered
- Government, industry, private foundations, and the international community are working in silos
- Lack of funding to support young investigators, innovation and bold ideas
OnPAR: Why is it different?

► OnPAR is a matchmaking platform that provides access to:
  – Previously unavailable, unfunded applications, and eventually pre-peer review ideas, failed drug candidates, and other research data
  – The most comprehensive and accurate global research landscape in one place
  – Analytic tools to mind data and inform your investment decisions

► OnPAR facilitates collaboration through a global network of resources that continues to expand
Proposed Solution: OnPAR with Dimensions

Provides improved data-driven, situational awareness about research projects and current funding investments to enhance future decision making

► Funding opportunities outside government
► Comprehensive database to avoid duplication
► Resources to develop informed research strategies
► Records of on-going and future research projects
A Knowledge Research Database & Network of Life Sciences Organizations

OnPAR Dimensions

- Unfunded Applications
- Funded Grants & Publications
- Analytics
- Network
- Marketing & Communications
OnPAR: How Does It Work?  
...Partners & Applicants

Partners join OnPAR

Work with Leidos to announce Program

Applicants register

Submit abstract

[If invited] Submit application and peer review summary
How Does It Work?

…Members

Become an OnPAR Member

Announcement and Marketing

Your Own OnPAR Portal

Unfunded Applications Submitted into OnPAR
Process Summary

Government Funding Agencies: Unfunded, off-priority applications

OnPAR: Submission and review

For- and Non-Profit: Funding
Submit Abstract: If unfunded and scored within 30 percentile
Submit Full Application & Summary Statement: By invitation only
Negotiate Final Grant/Contract with Member Organization: If selected for funding
Description of Project: Short summary or “abstract”

Post on OnPAR:
1) Review
2) Full access by request and explanation only

Negotiate Terms
OnPAR in the News

Editorial
► Funding Unfunded NIH Research Applications
Martin A. Dueñas, Isabelle Bisceglio, and James Pannucci; March 23, 2016.
*Science Translational Medicine Journal*
http://stm.sciencemag.org/content/8/331/331ed3

Funding Research Through the Online Partnership to Accelerate Research (OnPAR)
Martin A. Dueñas, Isabelle Bisceglio; September 2016
*JACC: Basic to Translational Science*
http://basic translational.onlinejacc.org/content/early/2016/09/08/j.jacbts.2016.08.005

NIH
► A Pilot Partnership to Find Private Support for Unfunded Applications
Michael Lauer, NIH Deputy Director for Extramural Research; March 23, 2016.
*NH Extramural Nexus, Open Mike.*
http://nexus.od.nih.gov/all/2016/03/23/a-pilot-partnership-to-find-private-support-for-unfunded-applications/
OnPAR in the News

General News
► New Funding Matchmaker Will Cater to NIH Rejects

► Leidos Launches Portal to Accelerate and Improve Biomedical Research Funding

► Finding Funding for Rejected NIH Proposals

► Second Chance for Rejected Grants
http://cen.acs.org/articles/94/i13/Second-chance-rejected-grants.html?type=paidArticleContent

► OnPAR: A Second Chance for Unfunded NIH Proposals
Jaclyn Lucas, April 12, 2016. Harvard University, Office of Sponsored Projects 
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Take home message:

► **For Applicants**: please submit your abstracts – *the more we get, the more members will join and the more opportunities for funding*

► **For Members (Foundations, Pharmaceuticals, VC)**: Join and have access to innovative research that can support your mission and internal R&D

► **For Agencies (Government and non-Government)**: Please join and help us provide unfunded applicants a second opportunity for funding
Appendix A

https://www.youtube.com/watch?v=aQuLpMPYzYM&feature=youtu.be
Leidos Life Sciences’ Complete Spectrum of Preclinical Services

Feasibility Assessment and Audit
- Pilot production
- Expression platform evaluation
- CMC characterization
- Animal studies
- Cell banking
- Facility audit

Assay Development
- Assay design, development, and validation
- Stability-indicating assays: design, development, and qualification

Process Development
- Product development plan
- Manufacturing and purification development
- Formulation studies
- Release, analytics, and stability assays
- Technology transfer

GMP Manufacturing
- Facility audit
- Characterization of FDP
- Product stability program
- Finish and fill
- cGMP drug product, vialing, and labeling

Tox and Safety Testing
- Mouse immunogenicity testing
- Efficacy testing
- GLP toxicity studies
- General safety testing
- GLP ADME studies

Managing and Conducting Clinical Trial Activities
- Protocol development
- Site assessment
- Clinical monitoring
- CRF development
- CSRs for products

Regulatory Support
- Pre-IND meeting
- IND preparation and submission to FDA
- Monitoring support during clinical life cycle
- In-house QA and QC

IT System and Security
- Documentation system
- Data confidentiality and sharing
- IT infrastructure and security

Repository
- Inventory storage of biological materials
- Shipment of samples and permits

Product Candidate at Leidos
- All tasks under one umbrella
- Cost effective
- No IP issue
- IT infrastructure and data security
- Complete services from bench to bedside

Leidos Proprietary
Leidos Corporate Overview

Vision: To be the global leader in the integration and application of information, technology, and systems to solve critical customer problems. We will deliver innovative solutions and services through the collaboration of our diverse and talented employees. We will empower our workforce, contribute to our communities, and operate sustainably.

Our new business is separated into five groups focused around four distinct markets and one cross-cutting market, which we call Advanced Solutions.

- **DEFENSE**: $3.0 billion revenue
- **CIVIL**: $2.7 billion revenue
- **INTELLIGENCE & HOMELAND SECURITY**: $2.7 billion revenue
- **HEALTH**: $1.6 billion revenue
- **ADVANCED SOLUTIONS**: $1.6 billion revenue

2016E $10B REVENUE
Thank you!

Martin Dueñas
Director, Health Research Management Practice
5202 Presidents Court, Suite 110 | Frederick, MD 21703
Tel: 202.905.4582 | Email: martin.a.duenas@leidos.com

OnPAR: https://onpar.leidosweb.com