



## Rediscovery Research Description



The Patient Impact Initiative will inspire scientists and clinicians (and other interested parties outside of medicine) to create and complete clinical trials and other Rediscovery Research to directly impact patients. This “Rediscovery Research” can impact patients by reusing, reconfiguring and combining already existing drugs and devices, modifying treatment protocols and testing clinical observations. These 1-3 year Rediscovery Research Projects can focus on any disease, use any therapy and impact any group of patients, as long as they meet with purpose of Rediscovery Research, to create better near term treatment options, improve early diagnosis and lengthen disease remission re-using science and medicine that has already been discovered once.

### What qualifies as Rediscovery Research?

The following are some examples of Rediscovery Research. It is likely that once the Patient Impact Initiative creates the incentive for Rediscovery Research, bright minds will find new ways to use reuse, combine and newly apply already available science and medicine to help patients.

1. repurposing an FDA approved drug or drug combinations to treat "off label" diseases
2. combining an older drug or a combination of older drugs with a newer drug to increase the newer drug effectiveness
3. combining a drug with a non-drug treatment option, such as radiation, to make the non-drug treatment work better
4. combining a non-drug treatment option with an available drug to make the drug work better
5. testing combinations of available drugs that are not currently prescribed together but are already used in one specific disease to see if the combination works better in that disease
6. scientifically testing combinations of vitamins, supplements and botanicals, that would be available to physicians and their patients, if efficacy can be proven
7. in limited circumstances, human clinical testing of new compounds, in rare diseases for which there is no current treatment, and there is strong likelihood of efficacy and accelerated approval
8. repurposing FDA approved devices to treat "off label" diseases
9. modifying current treatment protocols to make them work better and help more patients for longer periods of time, such as modifying the time of day of drug administration, reducing drug doses while increasing the frequency of drug administration to reduce side effects, testing radically lower doses of effective medicines that patients refuse because of side effects
10. scientifically testing clinical observations or sound clinical ideas, including those from integrative medicine or from other parts of the world

## Examples of Rediscovery Research

- Repurposing of thalidomide for multiple myeloma, then other blood cancers, other cancers, and non-oncologic diseases, and the development of Revlimid (**Repurposing Example 1 from above**)
- Testing the addition of NK cells to autologous stem cell transplants to improve the remission rate in non-Hodgkin's lymphoma (**Repurposing Example 9 from above**)
- Combining an old malaria drug with a new kinase inhibitor to help the kinase inhibitor work for more lung cancer patients for a longer period of time (**Repurposing Example 2 from above**)
- Creating life saving treatments for children with familial dysautonomia by screening and then proving that specific vitamins and botanical compounds increased the overall production of a critical protein (**Repurposing Example 6 from above**)
- Repurposing a device originally developed to help the blind “see” to significantly improve functional performance in multiple sclerosis and traumatic brain injury patients (**Repurposing Example 8 from above**)
- Repurposing a laser ablation device originally used to treat breast cancer to treat prostate cancer patients with a much low incidence of side effects such as incontinence and impotence (**Repurposing Example 8 from above**)
- Repurposing the pain medication buprenorphine for the interruption and maintenance of heroin and other opioid addictions (**Repurposing Example 1 from above**)
- Repositioning the anti-Parkinsonian drug Requip for the treatment of both Restless Legs Syndrome and SSRI-induced sexual dysfunction (**Repurposing Example 1 from above**)
- Repositioning anti-epileptics gabapentin and pregabalin for treating anxiety disorders and neuropathic pain. (**Repurposing Example 1 from above**)
- Proving that Hatha Yoga breathing and relaxation can be as effective a treatment for Generalized Anxiety Disorder as drugs or counseling (**Repurposing Example 10 from above**)



## Why Rediscovery Research?

There are thousands of potential treatments waiting to be rediscovered in the medicine and science that already exists. Of the top 50 selling pharmaceuticals in 2004, 84% have had additional indications approved since their initial US licensure (<http://www.msi.co.uk/drug-repurposing>). This type of Rediscovery Research provides

- low research costs and fast delivery of “new” effective treatments to patients by leveraging knowledge, resources and regulatory approvals already paid for through past research and clinical experience
- treatments that typically use low cost drugs and devices with known safety profiles, following slightly modified treatment protocols with which clinicians are already familiar
- significantly reduced healthcare costs created in a fraction of the time and expense

## Patient Impact Initiative- Rediscovery Research Description

The Patient Impact Initiative Rediscovery Research will take place at carefully selected academic research institutions, biotechs, pharmaceutical companies and large clinical practices. Administration will be centrally provided by the staff of the Partnership for Cures. Project reviews will be conducted by independent volunteer clinicians, scientists and lay reviewers from around the country using a fully electronic interface. Rediscovery Research Projects will ordinarily make an impact on patients in some manner in 1-3 years and can cost \$25,000-\$250,000 per year, with an emphasis on funding lower-cost grants.

### What is involved in the Patient Impact Initiative Grant Process?

All grant ideas will be initially submitted to the Patient Impact Initiative in the form of a **Grant Letter of Intent (LOI) and Pre-Proposal**. This reduces the time it takes for both your grant preparation and our reviewers' initial ranking and review.

A **Grant LOI and Pre-Proposal** includes:

- A very short LOI to be submitted within a few weeks of the Request for Proposal to hold the spot open for the Grant Pre-Proposal
- About 2.5 weeks later the Grant Pre-Proposal, which includes:
  - A 1-3 page description of the proposed research (1500 word max)
  - A budget and timeline
  - A description of how/when this Rediscovery Research could impact patient
  - The NIH Biosketch of the PI and full PI contact information

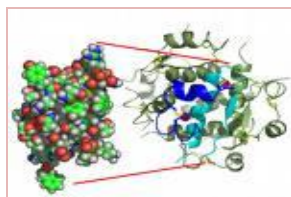
Grant Pre-Proposals will be reviewed and ranked. **The closer the research is to making a direct patient impact, the more likely it is to be highly ranked. Pilot or other clinical trials would be ideal. Cost effectiveness will be a key ranking criterion.**

If a Grant Pre-Proposal ranks high enough and funding is available, the PI will be asked to submit a more thorough NIH style grant proposal. At that point in time, the grant will have at least a 25% chance of being funded.

All Grant Pre-Proposals should be sent via e-mail to [Bruce@4cures.org](mailto:Bruce@4cures.org).

**Mission:** The mission of the Patient Impact Initiative is to secure funds to improve healthcare outcomes and reduce patient healthcare costs worldwide by financing, facilitating, and publicizing Rediscovery Research solutions that repurpose drugs, test clinical observations, and modify treatment protocols.

**Vision:** To create and manage a global collaboration of philanthropists, disease specific non-profits (VHOs), research institutions, researchers, patient support groups, industry, media and the lay public that raises and deploys funds to drive the development of near term Rediscovery Research solutions to patients that improve quality and length of life.



Dr. Bruce E. Bloom, President and Chief Science Officer, Partnership for Cures  
70 West Madison Street, Suite 1500 • Chicago, IL 60602 • 312-696-1366  
[Info@TeamPII.org](mailto:Info@TeamPII.org) [www.TeamPII.org](http://www.TeamPII.org)