

The logo for IMPACT features the word "IMPACT" in a serif font. Above the letters "M" and "P" is a stylized, curved line that arches over them, resembling a mountain range or a bridge. The logo is centered within a white rectangular box with a blue border.

IMPACT

**Initiative on Methods, Measurement,  
and Pain Assessment in Clinical Trials**

## What is IMMPACT is NOT

- ❖ International **M**aine **M**aritime **P**otato **A**ction **T**eam
- ❖ Initiative for **M**aternal **M**ortality **P**rogramme **A**ssessment
- ❖ International **M**icronutrient **M**alnutrition **P**revention and **C**ontrol **P**rogram
- ❖ **I**MMigrants **P**ublic **A**ction **C**oalition of **T**renton (NJ)
- ❖ Impact **M**edia **M**inistries
- ❖ **I**MM**p**act talent partners – talent acquisition for professional sports
- ❖ **I**mm**P**act: A prevention pact on healthy cattle, healthy market relationships.
- ❖ **D**ouble **I**mm**p**act **T**aekwondo: A martial art (something that would come in handy as we work toward bring a diverse group to consensus!)

## What IMMPACT Is

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- ❖ The **I**nitiative on **M**ethods, **M**easurement, and **P**ain **A**ssessment in **C**linical **T**rials
- ❖ International consortium of participants from academic research, governmental agencies (US FDA, US NIH, US VA, EMA), industry, consulting and research organizations, and consumer advocates
- ❖ **Mission:** To develop consensus recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain.

## Australia

- ◆ Univ Queensland

## Canada

- ◆ Dalhousie Univ
- ◆ London Reg Cancer Ctr
- ◆ Queen's Univ
- ◆ Univ Ottawa
- ◆ Univ Saskatchewan
- ◆ Univ Toronto
- ◆ York Univ

## Denmark

- ◆ Copenhagen Univ
- ◆ Odense Univ Hosp

## Finland

- ◆ Helsinki Univ

## Germany

- ◆ Heinrich Heine Univ
- ◆ Univ Heidelberg
- ◆ Univ Kiel
- ◆ Univ Munich

## Portugal

- ◆ Fac de Med de Lisboa

## Sweden

- ◆ Univ Uppsala

## United Kingdom

- ◆ Imperial Coll London
- ◆ Oxford Univ
- ◆ St Thomas Hosp
- ◆ Univ Bath
- ◆ Univ Glasgow
- ◆ University Hosp, Aintree

## United States

- ◆ Beth Israel Med Ctr
- ◆ Brigham & Women's Hosp
- ◆ Children's Hosp Boston
- ◆ Children's Hosp Cincinnati
- ◆ Children's Hospital Wisconsin
- ◆ Columbia Univ
- ◆ Denver Health Hosp
- ◆ Duke Univ
- ◆ Hackensack Univ Med Ctr
- ◆ Harvard Univ
- ◆ Johns Hopkins Univ
- ◆ Massachusetts General Hosp
- ◆ Med Coll Virginia
- ◆ MD Anderson Cancer Ctr
- ◆ Mt Sinai School of Medicine
- ◆ New York Psychiatric Institute
- ◆ Northwestern Univ
- ◆ Oregon Hlth & Sci Univ
- ◆ St. Francis Hosp Med Ctr
- ◆ St. Louis Univ
- ◆ Stanford Univ
- ◆ Thomas Jefferson Univ
- ◆ Tufts Univ
- ◆ Univ California, Los Angeles
- ◆ Univ California, San Diego
- ◆ Univ California, San Francisco
- ◆ Univ Chicago
- ◆ Univ Kentucky
- ◆ Univ North Carolina
- ◆ Univ Pennsylvania
- ◆ Univ Pittsburgh
- ◆ Univ Rochester
- ◆ Univ Texas, San Antonio
- ◆ Univ Texas, Houston
- ◆ Univ Washington
- ◆ Univ Wisconsin
- ◆ Vanderbilt Univ
- ◆ Wayne State Univ
- ◆ Yale Univ

## Representatives from:

- ❖ American Chronic Pain Association (ACPA)
- ❖ US Drug Enforcement Agency (DEA)
- ❖ European Medicines Agency (EMA)
- ❖ National Institutes of Health (NIH)
  - ◆ National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
  - ◆ National Cancer Institute (NCI)
  - ◆ National Institute of Child Health & Development (NICHD)
  - ◆ National Institute of Dental and Craniofacial Research (NIDCR)
  - ◆ National Institute of Drug Abuse (NIDA)
  - ◆ National Institute of Neurological Disorders & Stroke (NINCDS)
  - ◆ National Institute of Nursing Research (NINR)
- ❖ Rocky Mountain Poison & Drug Center
- ❖ Substance Abuse & Mental Health Service Administration (SAMSA)
- ❖ US Army
- ❖ US Food & Drug Administration (FDA)
  - ◆ Center for Drug Evaluation & Research (CDER)
  - ◆ Center for Devices & Radiological Health (CDRH)
- ❖ US Veterans Administration (VA)

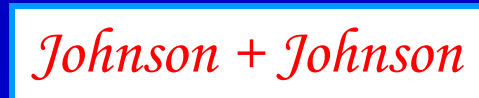
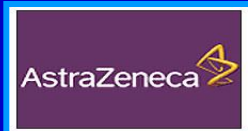
## Representatives from:

- ◆ Analgesic Solutions
- ◆ California Pacific Medical Center Res Inst
- ◆ Canadian Inst of Work & Health
- ◆ CNS Drug Consulting
- ◆ Colucci & Associates
- ◆ Covance
- ◆ Cytel
- ◆ Kendle Early Stage
- ◆ Lifetree Clinical Research
- ◆ McCormick Consultation
- ◆ MEDTAP International
- ◆ Rocky Mountain Poison & Drug Center



# Sponsors of IMMPACT

Support for meetings was provided by unrestricted educational grants to the University of Rochester Office of Professional Education by:



- IMMPACT-I: Outcomes Domains for Chronic Pain Clinical Trials**
- IMMPACT-II: Outcome Measures for Chronic Pain Clinical Trials**
- IMMPACT-III: Developing Measures of Pain-related PROs**
- IMMPACT-IV: Clinical Importance of Individual Patient Improvements**
- IMMPACT-V: Outcome Domains and Measures for Pediatric Trials**
- IMMPACT-VI: Analyzing Multiple Endpoints**
- IMMPACT-VII: Res Design Considerations for Confirmatory Chronic Pain Trials**
- IMMPACT-VIII: Outcome Domains and Measures for Acute Pain Trials**
- IMMPACT-IX: Res Design Considerations Proof-of-Concept Chronic Pain Trials**
- IMMPACT-X: Res Design Consideration for Clinical Studies of Abuse Deterrent Opioid Analgesics**
- IMMPACT-XI: Res Design Consideration for Clinical Trials of Pre-emptive Analgesia and the Prevention of Chronic Pain**
- IMMPACT-XII: Res Methods & Outcomes for Human Experimental & Clinical Studies Involving Abuse Liability of Analgesic Medications**
- IMMPACT-XIII: Recommendations for Improving Assay Sensitivity in Chronic Pain Clinical Trials**
- IMMPACT-XIV: Recommendations for Understanding & Interpretation of Analgesic Clinical Trial Results**



- ❖ Turk DC, Dworkin RH, Allen RR, et al. Core outcomes domains for chronic pain clinical trials: IMMPACT Recommendations. *Pain*. 2003;106:337-345.
- ❖ Dworkin R, Turk D, Farrar J, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2005;113:9-19.
- ❖ Turk DC, Dworkin RH, Burke LB, et al. Developing patient-reported outcome measures for pain clinical trials: IMMPACT recommendations. *Pain*. 2006;125:208-215.
- ❖ Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *Journal of Pain*, 2008;9:105-121.
- ❖ McGrath PJ, Walco G, Turk DC, et al. Core outcome domains and measures for pediatric acute and chronic/recurrent pain clinical trials: PedIMMPACT recommendations. *J Pain*. 2008;9:771-783.
- ❖ Turk DC, Dworkin RH, McDermott MP, et al. Analyzing multiple endpoints in clinical trials of pain treatments: IMMPACT recommendations. *Pain*, 2008;139:485-493.
- ❖ Dworkin RH, Turk DC, McDermott MP, et al. Interpreting the clinical importance of group differences in chronic pain clinical trials: IMMPACT recommendations. *Pain*, 2009;146:238–244.
- ❖ Dworkin RH, Turk DC, Peirce-Sandner S, et al. Research design considerations for confirmatory chronic pain clinical trials: IMMPACT recommendations. *Pain*, 2010;149:177-193.



# What IMMPACT Does: Consensus Publications

❖ Stephen Cohen, Desjardins P, Turk DC, Dworkin RH, Ballantyne JC, Blum DE, Burke LB, Carragee E, Costello A, Cowan P, Croll S, Dionne R, Farrar JT, Gammaitoni AR, Gilron I, Gordon DB, Hertz S, Iyengar S, Jay G, Kalso E, Katz NP, Kehlet H, Kerns RD, McDermott MP, McQuay HJ, Permutt T, Price D, Raja SN, Rappaport BA, Rauschkolb C, Royal M, Segerdahl M, Stauffer JW, Todd KH, Vanhove T, Wallace MS, West C, White RE, Wu C. Research methods and outcomes for acute pain clinical trials: IMMPACT recommendations. Manuscript in preparation.

❖ Dworkin RH, Turk DC, Peirce-Sandner S, Baron R, Costello A, Cowan P, Desjardins P, Dimitrova R, Dionne R, Farrar JT, Gastonguay M, Gilbert PR, Gilron I, Hertz S, Hewitt DJ, Iyengar S, Jay G, Kalso E, Katz NP, Kerns RD, Leff R, Leong M, McDermott MP, McQuay HJ, Mehta C, Petersen KL, Raja SN, Ravina BM, Rappaport BA, Rauschkolb C, Rice ASC, Rowbotham MC, Sampaio C, Senn S, Sindrup S, Stauffer JW, Steigerwald I, Stewart J, Taylor C, Tobias J, Treede RD, Wallace M, White RE. Research design considerations for proof-of-concept chronic pain clinical trials: IMMPACT recommendations. Draft manuscript being finalized for circulation to authors.

❖ Comer SD, Zacny JP, Bigelow GE, Foltin R, Jasinski DR, Sellers EM, Dworkin RH, Turk DC, Adams EH, Balster R, Burke LB, Cerny I, Colucci R, Cone E, Cowan P, Farrar JT, Haddox JD, Haythornthwaite JA, Hertz S, Jay G, Johanson C-E, Junor R, Katz NP, Klein M, Kopecky E, Leiderman DB, McDermott M, O'Brien C, O'Connor AB, Palmer PP, Raja SN, Rappaport BA, Rauschkolb C, Rowbotham MC, Sampaio C, Setnick B, Sokolowska M, Stauffer JW, Walsh SL. Outcome measures for human experimental studies of the abuse liability of analgesic medications. Draft manuscript being finalized for circulation to authors.

- ❖ Turk DC, O'Connor AB, Dworkin RH, Chaudhry A, Adams EH, Brownstein J, Comer SD, Dart R, Dasgupta N, Denisco RA, Katz NP, Klein M, Leiderman DB, Rappaport BA, Zacny JP, Ahdieh H, Burke LB, Cowan P, Jacobs P, Lubran R, Malamut R, Markman JD, Michna E, Palmer P, Peirce-Sandner S, Raja SN, Rauschkolb C, Roland C, Sannerud CA, Sharpe-Potter J, Tella SR, Webster LR, Weiss RD, Woolf K. Research design considerations for clinical studies of abuse-deterrent opioid analgesics. Draft manuscript being finalized for circulation to authors.
- ❖ Cooper S, Desjardins P, Turk DC, Dworkin RH, Ballantyne JC, Blum DE, Burke LB, Carragee E, Costello A, Cowan P, Croll S, Dionne R, Farrar JT, Gammaitoni AR, Gilron I, Gordon DB, Hertz S, Iyengar S, Jay G, Kalso E, Katz NP, Kehlet H, Kerns RD, McDermott MP, McQuay HJ, Permutt T, Price D, Raja SN, Rappaport BA, Rauschkolb C, Royal M, Segerdahl M, Stauffer JW, Todd KH, Vanhove T, Wallace MS, West C, White RE, Wu C. Research methods and outcomes for acute pain clinical trials: IMMPACT recommendations. Manuscript in preparation.



# What IMMPACT Does: Commissioned Papers, Studies, & Publications

- ❖ Jensen MP. Validity and Reliability of Pain Measures for Use in Clinical Trials of Adults. Paper presented at the IMMPACT-II meeting, Washington, D.C., April 12, 2003. Available at [IMMPACT.org](http://IMMPACT.org)
- ❖ Stucki G, Cieza A. HRQOL Measures in Chronic Pain Trials. Paper presented at the IMMPACT-II meeting, Washington, D.C., April 12, 2003. Available at [IMMPACT.org](http://IMMPACT.org)
- ❖ Haythornthwaite JA. The Assessment of Pain-Related Physical Function for Clinical Trials in Chronic Pain. Paper presented at the IMMPACT-II meeting, Washington, D.C., April 12, 2003. Available at [IMMPACT.org](http://IMMPACT.org)
- ❖ Kerns RD. Assessment of Emotional Function in Pain Treatment Outcome Research. Paper presented at the IMMPACT-II meeting, Washington, D.C., April 12, 2003. Available at [IMMPACT.org](http://IMMPACT.org)
- ❖ Stinson JN, Kavanagh T, Yamada J, Gill N, Stevens S. Systematic review of the psychometric properties, interpretability and feasibility of self-report pain intensity measures for use in clinical trials in children and adolescents. *Pain*, 2006;125:143-157.
- ❖ von Baeyer C, Spagrud LJ. Systematic review of observational (behavioral) measures of pain for children and adolescents aged 3 to 18 years. *Pain*, 2007;127:140-150.
- ❖ Turk DC, Dworkin RH, Revicki D, et al. Identifying important outcome domains for chronic pain clinical trials: an IMMPACT survey of people with pain. *Pain*, 2008;137:276–285.

## **What IMMPACT Does: Commissioned Papers, Studies , & Publications**

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- ❖ **Dworkin RH, Turk DC, Revicki D, et al. Development and initial validation of an expanded and revised version of the Short-form McGill Pain Questionnaire (SF-MPQ-2). Pain, 2009;144:35-42.**
- ❖ **Dworkin RH, Turk DC, Peirce-Sandner S, et al. Placebo and treatment group responses in postherpetic neuralgia vs. painful diabetic peripheral neuropathy clinical trials in the REPORT database. Pain, 2010;150:12-16.**
- ❖ **Dworkin RH, Peirce-Sandner S, Turk DC, McDermott MP, Gibofsky A, Simon LS, Farrar JT, Katz NP. Outcome measures in placebo-controlled trials of osteoarthritis: responsiveness to treatment effects in the REPORT database. Osteoarthritis & Cartilage in press.**

# What IMMPACT Does: Creation of Clinical Trials Databases

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- ❖ Creation of **R**esource for **E**valuating **P**rocedures and **O**utcomes of **R**andomized **T**rials (REPORT) databases
- ❖ Extracts methodological information from published randomized clinical trials
- ❖ Current databases created
  - ◆ Osteoarthritis
  - ◆ Neuropathic Pain
- ❖ Databases in development
  - ◆ Fibromyalgia
  - ◆ Back Pain
  - ◆ Acute Postsurgical Pain

- ❖ Publications have been cited several hundred times
- ❖ Cited in over 150 of scientific publications, including:

## Pain Journals

- |  |                          |
|--|--------------------------|
| ◆ American Pain Society (APS) Bull     | ◆ Pain                   |
| ◆ Anaesthesia, Pain and Intensive Care | ◆ Pain: Clinical Updates |
| ◆ Clin J Pain                          | ◆ Pain Management Today  |
| ◆ Current Pain & Headache Rep          | ◆ Pain Med               |
| ◆ Douleur et Analgesie                 | ◆ Pain Physician         |
| ◆ Eur J Pain                           | ◆ Pain Practice          |
| ◆ Headache                             | ◆ Pain Res & Manage      |
| ◆ J Musculoskeletal Pain               | ◆ Scand J Pain           |
| ◆ Journal of Orofacial Pain            | ◆ Schmerz                |
| ◆ J Pain                               |                          |
| ◆ J Pain Symptom Manage                |                          |
| ◆ J Soc Pain Nursing                   |                          |
| ◆ Neuromodulation                      |                          |

## General medical journals including:

- ◆ Acta Medica Portugese
- ◆ Am J Med
- ◆ BMC Med
- ◆ BMC Med Res & Methods
- ◆ Brain
- ◆ Brain Res
- ◆ Clin Geriatr Med
- ◆ Clin Therapeutics
- ◆ Cochrane Database Syst Rev
- ◆ Diagnostica
- ◆ Int J Clin Pract
- ◆ Int J Med Res
- ◆ JAMA
- ◆ J Clin Epidemiol
- ◆ J Med Economics
- ◆ J Women's Health
- ◆ Lancet
- ◆ Mayo Clinic Proceedings
- ◆ Med Clin North America
- ◆ Med J Australia
- ◆ MMW-Fortschritte der Medizin
- ◆ Nature Med
- ◆ PLoS Medicine
- ◆ PLoS ONE
- ◆ Presse Medicale



## Pharmacology

- ◆ Alimentary Pharmacol Therapeutics
- ◆ Br J Pharmacol
- ◆ Clin Therapeutics
- ◆ Curr Pharmaceutical Design
- ◆ Curr Pharmacological Decisions
- ◆ Drugs of Today
- ◆ Expert Opin on Biological Ther
- ◆ Expert Opin on Pharmacotherapy
- ◆ Expert Opin on Therapeutic Patents
- ◆ Expert Rev of Neurotherapeutics
- ◆ Expert Rev Pharmacoeconomics  
Outcomes Res
- ◆ Fundamental & Clinical Pharmacol
- ◆ Future Drugs
- ◆ Inflammopharmacol
- ◆ Int J Clin Psychopharmacol
- ◆ Nature Rev Drug Discovery
- ◆ Neuropsychopharmacology
- ◆ Trends in Pharmacological Sci
- ◆ Trials

## Oncology

- ◆ Cancer
- ◆ Cancer Nursing
- ◆ Clin Cancer Res
- ◆ Clin Oncol
- ◆ Eur J Cancer
- ◆ Int J Radiation Oncology  
Biology Physics
- ◆ J Palliative Med
- ◆ Oncologie
- ◆ Oncologist
- ◆ Oncol Nurs Forum
- ◆ Supportive Care in Cancer
- ◆ Tumor Diagnostik und  
Therapy

## Addiction

- ◆ Am J Addictions
- ◆ Am J Drug Alcohol Abuse

## **Orthopedics/Neurosurg/Rehabil**

- ◆ Arch Phys Med & Rehabil
- ◆ BMC Musculoskeletal Disord
- ◆ Br J Neurosurgery
- ◆ Clinic Kinesiol
- ◆ Clinical Rehabil
- ◆ Disabil Rehabil
  
- ◆ EurSpine J
- ◆ Joint Bone Spine
- ◆ J Bone & Joint Surgery
- ◆ J Ortho Sports Phys Ther
- ◆ J Rehabil Res & Develop
- ◆ J Spinal Cord Med
- ◆ Physical Therapy
- ◆ PM&R
- ◆ Revista Brasileira de Medicina do Esporte
- ◆ Spinal Cord
- ◆ Spine
- ◆ Spine J

## **Anesthesiology**

- ◆ Acta Anaesth Scand
- ◆ Anesthesiology
- ◆ Anasthesiologie Intensivmedizin Notfallmedizin Schmerztherapie
- ◆ Anesthesia & Analgesia
- ◆ Br J Anaesthesiology

## **Rheumatology**

- ◆ Arthritis Care Res
- ◆ Arthritis Res Ther
- ◆ Clin Experimental Rheumatol
- ◆ Clin Rheumatol
- ◆ Current Rheumatology Rep
- ◆ J Rheumatol
- ◆ Revue du Rhumatisme
- ◆ Rheumatic Dis Clin of North America
- ◆ Rheumatology

## **Neurology**

- ◆ Am J Neurol
- ◆ Ceska a Slovenska Neurologie a Neurochirurgie
- ◆ Eur J Neurol
- ◆ Multiple Sclerosis
- ◆ Nervenheilkunde
- ◆ Neurology
- ◆ Parkinson's Dis

## **Obstetrics/Gynecology/Reproductive Med**

- ◆ Archives Gyneol Obstetr
- ◆ Fertility Sterility
- ◆ Obstetr Gynaecol
- ◆ Obstetr Gynaecol Survey

## Psychology/Psychiatry

- ◆ Ann Behav Med
- ◆ Applied Psychophysiology & Biofeedback
- ◆ Behav Ther
- ◆ Canad Rev Psychiat
- ◆ Cogn Behav Pract
- ◆ Gen Hosp Psychiat
- ◆ Health Psychol
- ◆ Int J Behav Med
- ◆ Int J Clin Exper Hypnosis
- ◆ J Behav Med
- ◆ J Clin Psychol: In Session
- ◆ J Clin Psychol in Medical Settings
- ◆ J Nervous Mental Dis
- ◆ J Pediatric Psychol
- ◆ J Psychosomatic Res
- ◆ Rehabil Psychol
- ◆ Revue Europeene de Psychologie Appliquee

## Internal Medicine

- ◆ Arch Internal Med
- ◆ Clin Infectious Dis
- ◆ Diabetes Med

## Dentistry

- ◆ J Endodontics
- ◆ J Oral Rehabil
- ◆ Oral Surgery Oral Medicine Oral Pathology Oral Radiology & Endodontics

## Other

- ◆ Acad Emerg Med
- ◆ Acta Dermato-Venereologica
- ◆ Acta Paediatrica
- ◆ Am J Emerg Med
- ◆ Am J Gastroenterology
- ◆ Am J Veterinary Res
- ◆ Burns
- ◆ Child Adoles Men Hlth
- ◆ Complementary Ther in Med
- ◆ Current Eye Res
- ◆ Eur Arch Oto-Rhino-Laryngol
- ◆ Head & Neck
- ◆ Hernia
- ◆ Health Technology Assessment
- ◆ Intl J Eating Dis
- ◆ J Investigational Radiol
- ◆ J Manip Physiol Thera
- ◆ J Neurosurg
- ◆ Med Acupuncture
- ◆ Neuroscience Letters
- ◆ Padiatria Polska
- ◆ Physiological Measurement
- ◆ Quality of Life Research
- ◆ Sleep Medicine
- ◆ Topics in Advanced Practice Nursing eJournal
- ◆ World J Surgery



## Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

The mission of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) is to develop consensus reviews and recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain. The first IMMPACT meeting was held in November 2002, and there have been a total of nine consensus meetings on clinical trials of treatments for pain—seven on trials for chronic pain in adults, one on trials for acute pain in adults, and one on trials for pediatric acute and chronic pain. Invited participants come from academia, regulatory agencies (US Food and Drug Administration, European Agency for the Evaluation of Medicinal Products), US National Institutes of Health, US Veterans Administration, consumer support and advocacy groups, and industry. The disciplines represented at meetings varies but has included anesthesiology, clinical pharmacology, internal medicine, law, neurology, nursing, oncology, outcomes research, psychology, rheumatology, and surgery. For all IMMPACT meetings, an attempt is made to include broad representation while limiting the size of the meeting to promote vigorous and frank discussion and debate.

IMMPACT recommendations and systematic reviews have been widely cited and have guided the design of clinical trials, other types of clinical research, and a national survey. Additional consensus meetings are planned, and research initiatives involving the assessment of pain and the design and interpretation of clinical trials are ongoing. IMMPACT has received favorable responses from all of its stakeholders, who believe that this multidisciplinary initiative has made significant contributions to improved understanding of pain and its treatment.

For additional information about IMMPACT, please contact either Robert H. Dworkin, PhD, at [robert\\_dworkin@urmc.rochester.edu](mailto:robert_dworkin@urmc.rochester.edu) or Dennis C. Turk, PhD, at [turkdc@u.washington.edu](mailto:turkdc@u.washington.edu). For questions about the IMMPACT website, please contact Lili A. Dworkin at [ldworkin@haverford.edu](mailto:ldworkin@haverford.edu).

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The logo for IMPACT features the word "IMPACT" in a bold, serif font. Above the letters "M", "P", and "A" is a thin, dark, curved line that arches over them, resembling a stylized mountain range or a protective shield.

**IMPACT**

**Future????**