Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
What is IMMPACT is NOT

- International Maine Maritime Potato Action Team
- Initiative for Maternal Mortality Programme Assessment
- International Micronutrient Malnutrition Prevention and Control Program
- IMMigrants Public Action Coalition of Trenton (NJ)
- Impact Media Ministries
- IMMpact talent partners – talent acquisition for professional sports
- ImmPact: A prevention pact on healthy cattle, healthy market relationships.
- Double Immpact Taekwondo: A martial art (something that would come in handy as we work toward bringing a diverse group to consensus!)
What IMMPACT Is

- The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

- 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.
Who is IMMPACT -- Universities & Academic Medical Centers

**Australia**
- Univ Queensland
- Univ Ottawa
- Univ Saskatchewan
- Univ Toronto
- York Univ

**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**
- Helsinski Univ

**Germany**
- Heinrich Heine Univ
- Univ Heidelberg
- Univ Kiel
- Univ Munich

**Portugal**
- Fac de Med de Lisboa
- Univ Uppsala

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

**United Kingdom**
- Children’s Hosp Boston
- Children’s Hosp Cincinnati
- Children’s Hospital Wisconsin
- Columbia Univ
- Denver Health Hosp
- Duke Univ
- Hackensach 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

**United States**
- Beth Israel Med Ctr
- Brigham & Women’s Hosp
- Children’s Hosp Boston
- Children’s Hosp Cincinnati
- Columbia Univ
- Denver Health Hosp
- Duke Univ
- Hackensach 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
Who is IMMPACT – Government Agencies & Organizations

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)
Who is IMMPACT – Consulting & Research Organizations

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

Sponsors of IMMPACT

This space is available
| 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 |


What IMMPACT Does: Consensus Publications


What IMMPACT Does: Consensus Publications


What IMMPACT Does: Commissioned Papers, Studies, & Publications


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What IMMPACT Does: Creation of Clinical Trials Databases

- Creation of **Resource for Evaluating Procedures and Outcomes of Randomized Trials (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
Impact of IMMPACT

- Publications have been cited several hundred times
- Cited in over 150 of scientific publications, including:
  
  **Pain Journals**
  
  - American Pain Society (APS) Bull
  - Anaesthesia, Pain and Intensive Care
  - Clin J Pain
  - Current Pain & Headache Rep
  - Douleur et Analgesie
  - Eur J Pain
  - Headache
  - J Musculoskeletal Pain
  - Journal of Orofacial Pain
  - J Pain
  - J Pain Symptom Manage
  - J Soc Pain Nursing
  - Neuromodulation
  - Pain
  - Pain: Clinical Updates
  - Pain Management Today
  - Pain Med
  - Pain Physician
  - Pain Practice
  - Pain Res & Manage
  - Scand J Pain
  - Schmerz
Impact of IMMPACT

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
# Impact of IMMPACT

## 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
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<tr>
<th>Psychology/Psychiatry</th>
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<tr>
<td>Ann Behav Med</td>
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<td>Health Psychol</td>
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<td>Int J Behav Med</td>
<td>Child Adoles Men Hlth</td>
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<td>Int J Clin Exper Hypnosis</td>
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<td>J Investigational Radiol</td>
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<td>Revue Europene de Psychologie Appliquee</td>
<td>J Manip Physiol Thera</td>
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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 or Dennis C. Turk, PhD, at turkdo@u.washington.edu. For questions about the IMMPACT website, please contact Lili A. Dworkin at ldworkin@haverford.edu.
Future????