Advancing Public Health Through Clinical Trials Transparency

Harvard Medical School, March 23, 2015

Joanne Waldstreicher, M.D. J&J Chief Medical Officer
Johnson & Johnson: Diverse Health Care Innovation

1800s
- First commercial FIRST AID KITS
- First TOOTHPASTE in a tube
- MATERNITY KITS to make childbirth safer
- JOHNSON'S® BABY POWDER
- BAND-AID® BRAND First commercial dressings for small wounds
- First prescription CONTRACEPTIVE GEL

1900
- CHARNLEY® HIP First low-friction hip implant
- HALDOL® Gold standard for schizophrenia
- First one-week disposable contact lenses
- FIRST AID KITS
- ACUVUE®
- First CORONARY and DRUG-ELUTING STENT
- LCS® TOTAL KNEE SYSTEM First mobile bearing knee system
- SUN DOWN® First ever sunscreen introduced in Brazil

2000
- AVEENO® launches patented formula for UV protection
- LAPAROSCOPIC-CHOLECYSTECTOMY Ethenic Endo Surgery
- GENESearch BLN Diagnostic test for early cancer detection
- ZYTIGA® treatment for Prostate Cancer
- SIRIUTO® first new treatment for MDR-TB in over 40 years
- IMBRUVICA® new treatment for B-cell malignancies
- OLYSIO® new treatment for hepatitis C

2013
- COMPEED® cold sore patch: First to treat cold sore as wound
- MOTRIN® provided first Fever Treatment Guide in China

2014
- THERMOCOOL SMARTTOUCH® First catheter to provide direct & real-time measurement of contact force against heart wall
Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customer orders must be entered promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens — support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.
Our Commitment to Patients and Consumers

- Advocates and advisors for a patient- and consumer-centered view
- Catalysts of innovative safety and public health solutions
- Champions of medical ethics and benefit-risk assessment
- Promoters of excellence in scientific and medical capabilities
- Drivers of data transparency to inform and advance public health
Our Commitment to Patients and Consumers

Catalysts of innovative safety and public health solutions

Advocates and advisors for a patient- and consumer-centered view

Champions of medical ethics and benefit-risk assessment

Promoters of excellence in scientific and medical capabilities

Drivers of data transparency to inform and advance public health
Key Benefits of Sharing

- Maximizes contributions of participants and avoids unnecessary duplicative trials
- Allows other investigators to carry out additional analyses and reproduce published findings
- Strengthens evidence base for regulatory and clinical decisions
- Increases scientific knowledge gained from investments by funders
- Stimulates new ideas and raises the bar for research
Key Risks and Challenges

• Protect participant privacy and honor consent
• Safeguard legitimate economic interests
• Guard against invalid secondary analyses
• Give researchers time to conduct analyses and credit for sharing
Data Sharing Principles and Their Application

• Respect individual participants and their contributions
• Increase public trust in clinical trials
• Conduct clinical trial data sharing in a fair manner
• Stimulate and support a healthy R&D ecosystem
Pharmaceuticals

Medical Devices

Johnson & Johnson Will Make Clinical Data Available to Outside Researchers

By KATIE THOMAS JUN 14, 2015

The health care giant Johnson & Johnson has agreed to make detailed clinical trial data on its medical devices and diagnostic tests available outside researchers through a collaboration with Yale University, making it the first major company to do so.

The Access to Janssen Clinical Trial Data website is an outgrowth of the Yale Open Data Access Project (YODA Project), which seeks to advance the responsible sharing of clinical research data, open science, and research transparency. The project is committed to supporting research focused on improving the health of patients and informing policymakers.

Ours is an era of innovation, but the tools of innovation are not always available to everyone. This is what Johnson & Johnson is changing. They will make their data available to breakthrough research that could change the world.

At Johnson & Johnson, we believe that the sharing of clinical trial data can help advance science and medicine. We are committed to supporting research that will improve the health of patients and inform policymakers.

As part of our commitment to sharing data, we have launched Access to Janssen Clinical Trial Data. This website provides access to clinical trial data that we have collected for our medical devices and diagnostic tests.

The data can be used for research purposes, but it cannot be used for commercial or marketing purposes.

At Johnson & Johnson, we are dedicated to advancing science and medicine for the benefit of society. We believe that open science and transparency are essential to achieving this goal.

We hope that this website will be a valuable resource for researchers, and we encourage you to explore the data that we have made available.

Thank you for your interest in Johnson & Johnson’s work in advancing science and medicine.
<table>
<thead>
<tr>
<th>YODA Project</th>
<th>Johnson &amp; Johnson</th>
<th>Investigators</th>
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<tbody>
<tr>
<td>Independent</td>
<td>Ensure study meets agreed criteria</td>
<td>Provide specific details about self, research intent</td>
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<tr>
<td>Single point of contact for investigators</td>
<td>Seek to acquire approvals from partner companies</td>
<td>Provide statistical analysis plan</td>
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<tr>
<td>Advisory steering committee and external experts</td>
<td>Determine data availability</td>
<td>Submit publication plan</td>
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<tr>
<td>Decision-making authority</td>
<td>Provide date in accessible form</td>
<td>Sign Data Use Agreement</td>
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YODA Project Metrics, March, 2015

- Full research proposals approved: 8
- Trials requested that were unavailable: 14
  - Trial out of scope (e.g., ongoing, completed <18 months, phase): 6
  - Regulatory approval not yet received: 1
  - Partner has not agreed to share data through YODA Project: 6
  - Janssen is not the market authorization holder: 1
  - Trial materials not available in English: 1
<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Product</th>
<th>Research Proposal</th>
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<tbody>
<tr>
<td>UCSD</td>
<td>REMICADE</td>
<td>Post hoc analysis of the ACT-1 &amp; ACT-2 trials to simulate individualized dosing</td>
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<td></td>
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<td>regimens using a predictive model</td>
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<td>NIAMS, NIH</td>
<td>SIMPONI</td>
<td>Comparative effectiveness of tumor necrosis factor alpha inhibitors in ankylosing</td>
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<td></td>
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<td>spondylitis</td>
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<tr>
<td>Michigan State</td>
<td>RISPERDAL CONSTA</td>
<td>Understand the role that improved emotional dysregulation indicators play when</td>
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<td></td>
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<td>risperidone is used to treat conduct problems.</td>
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<td>UAB School of Medicine</td>
<td>ZYTIGA</td>
<td>Response Evaluation Criteria in Solid Tumors as a surrogate endpoint in metastatic</td>
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<td>castration-resistant prostate cancer</td>
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<tr>
<td>University of Maryland, Baltimore</td>
<td>REMICADE</td>
<td>Gender differences in weight gain in patients with inflammatory bowel disease</td>
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<td></td>
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<td>treated with Infliximab</td>
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<td>University of Copenhagen,</td>
<td>INVOKANA</td>
<td>The effects of SGLT-2 inhibitors in patients with type 2 diabetes: a systematic</td>
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<td>review with meta-analysis of randomised trials</td>
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<td>Technische Universität München</td>
<td>INVEGA&amp;RIS</td>
<td>Initial severity and efficacy of antipsychotics for schizophrenia and bipolar</td>
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<td>mania: Individual patient level analyses of placebo-controlled trials</td>
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<tr>
<td>U Michigan</td>
<td>REMICADE</td>
<td>Can machine learning algorithms using general labs predict biologic remission for</td>
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<td>patients on thiopurines in the SONIC trial?</td>
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Together, we will strengthen our trust with patients and consumers.

Together, we will make a difference in the world.