



Drugs in development – the research pipeline

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Clinical research

- Why study clinical research?
 - Important to develop new safe and effective treatments for psoriasis and psoriatic arthritis
- How are new treatments studied?
 - Clinical trials regulated by the U.S. Food and Drug Administration (FDA)
- How are clinical trials funded?
 - Industry or government

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Phases of drug development

Pre-clinical	Studies in the laboratory prior to studies in people.
Phase I	Is it safe? Phase determines how drug works in healthy individuals.
Phase II	Is it effective? Determines if drug is beneficial against a particular condition (100 patients).
Phase III	Can it be used in more patients? Drug is studied in a larger population (1,000 patients)
Phase IV	Can it be used in different types of patients? Drug is approved but studies may continue in a specific group of patients.

Definitions

- **RANDOMIZED TRIAL:** A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial.
- **ARM:** Any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more
- **PLACEBO CONTROLLED STUDY:** A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.
- **DOUBLE-BLIND STUDY:** A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy).

Research pipeline

- Provides information about drugs in development
- Maintained by companies and frequently found on company web site
- National Psoriasis Foundation Pipeline
 - Contains information in the public domain about drugs in development for psoriasis and psoriatic arthritis
 - Updated throughout the year
 - <http://www.psoriasis.org/research/pipeline/chart.php>

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Drugs approved in past 18 months

Name	Company	Delivery mechanism	Mechanism of action	Date	Indication
Clobex spray (Clobetasol propionate)	Galderma	topical	steroid	January 2006	Psoriasis
Humira (Adalimumab)	Abbott Immunology	injectable	TNF-alpha inhibitor	October 2005	Psoriatic arthritis
Remicade (Infliximab)	Centocor, Inc.	injectable	TNF-alpha inhibitor	May 2005	Psoriatic arthritis
Taclonex (Calcipotriene/betamethasone dipropionate)	Warner Chilcott	topical	anti-inflammatory and cell growth inhibitor	February 2006	Psoriasis



For more information

- For more information on clinical trials or participating in a clinical trial
 - <http://www.psoriasis.org/research/trials/>
 - <http://www.clinicaltrials.gov/>

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