

**WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF  
2013 to 2015**

**WORLD'S TOP 10 MEDICAL INNOVATIONS 7 FDA  
APPROVED DRUGS LIST OF 2013 TO 2015**

(This report presented in partial fulfilment of the requirement for the degree of bachelor of  
pharmacy)



**Submitted By**

Rukayya Aliyu Takuma

121-29-407

7<sup>th</sup> Batch

Department of Pharmacy

Faculty of Allied Health Science

Daffodil International University

Date of Submission: 24.03.2016

**WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF  
2013 to 2015**

**WORLD'S TOP 10 MEDICAL INNOVATIONS 7 FDA  
APPROVED DRUGS LIST OF 2013 TO 2015**

(This report presented in partial fulfilment of the requirement for the degree of bachelor of  
pharmacy)



**Daffodil**  
*International*  
**University**

**Submitted By**

Rukayya Aliyu Takuma

121-29-407

7<sup>th</sup> Batch

Department of Pharmacy

Faculty of Allied Health Science

Daffodil International University

Date of Submission: 24.03.2016

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **APPROVAL**

This project, world's top 10 medical innovations & FDA approved drugs list of 2013 to 2015, submitted by ID:121-29-407 department of pharmacy, daffodil international university, has been accepted as satisfactory for the partial fulfillment of the requirements for the degree of bachelor of pharmacy and approved as to its style and contents.

## **BOARD OF EXAMINERS**

### **Head**

### **Internal Examiner 1**

### **Internal Examiner 2**

### **External Examiner**

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **DECLARATION**

I hereby declare that, this project report is done by me under the supervision of Farhana Israt Jahan, Senior Lecturer, Department of Pharmacy, Faculty of Allied Health Sciences, Daffodil International University, Dhaka. I am declaring that this project is my original work. Neither this copy nor any part of thereof has been submitted elsewhere for the award of Bachelor or any degree.

### **Supervised By:**



09/04/16

---

Farhana Israt Jahan

Senior Lecturer

Department of Pharmacy

Faculty of Allied Health Science

Daffodil International University

### **Submitted By:**



---

Rukayya Aliyu Takuma

121-29-407

7<sup>th</sup> Batch, sec: B

Department of Pharmacy

Daffodil International University

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **DEDICATION**

This project is dedicated to my father, who taught me that the best kind of knowledge to have is that which is learned for its own sake. It is also dedicated to my mother, who taught me that even the largest task can be accomplished if it is done one step at a time.

**ACKNOWLEDGEMENTS**

All praises and gratitude to almighty Allah, the most beneficent and the merciful who enables me to finish my project work.

Then, I would like to express my appreciation to Farhana Israt Jahan, Senior lecturer of the Department of Pharmacy, Daffodil International University who has been the ideal project supervisor. Her sage advice, insightful criticisms and patient encouragement aided the writing of this project in innumerable ways.

I am also thankful to my Father Alhaj Aliyu Takuma, my mother Alhaj Fatima Aliyu Takuma, my sister and her husband Mr. & Mrs. Adamu Salisu without them my total study would be undone. And my very good friend Musa Uthman Hassan whom together with this project is completed.

Finally, I want to express my gratitude to my parent, my relatives and my friends who accepted to share their knowledge and experience.

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **ABSTRACT:**

The last several decades have seen tremendous progress in the medical science, research, and technologies that can be used to prevent and fight many diseases. In this study research on innovations in healthcare organizations published between 2013 to 2015 are here reviewed and summarized. Based on the overview of research, the paper discusses a fundamental change in perspective on innovation in the life sciences, towards a stronger emphasis on innovation as solving medical problems rather than technology development, the importance of clinical knowledge and clinical practices for innovation. The majority of identified studies deal with the adoption of innovations and new practices and were cross-sectional designs applying quantitative methods, or multiple case studies applying qualitative methods. Five pathways for future research are recommended: (a) Multilevel approaches studying innovation simultaneously on individual, group, and organizational levels; (b) a combination of quantitative and qualitative data; (c) use of longitudinal designs (innovation both as the dependent and independent variable); (d) application of experimental designs in interventions; and (e) exploration of innovation generation and structural innovations.

# WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

## Table of Content:

Chapter 1	Introduction...	Page No
	Definition of Medical Innovation	02
	Definition of Drug	03
	Meaning and definition of FDA.	03
	Responsibilities of FDA.	03
	How drug should be approved by FDA.	03
	Types of treatment methods in the world.	04-09
Chapter 2	Significance of the study	11
Chapter 3	Methodology	13
Chapter 4	Findings of the study	15
4.1	World top 1 medical innovations 2013...	15
	Bariatric surgery for control of diabetes.	15-16
	Neuromodulation therapy for cluster and migraine headaches.	16
	Mass spectroscopy for Bacterial Identification.	16
	Novel Medication for Advance Prostate Cancer.	17
	Handheld Optical Scan for Melanoma.	17
	Femtosecond Laser cataract Surgery.	17-18
	Ex vivo Lung Perfusion.	18
	Modulator Device for Treating Complex Aneurysm.	18
	Breast Tomosynthesis.	19
	Health Insurance / Medicare Program / Rewards for Better Health.	19
4.2	World top 10 medical innovations 2014...	20
	B Cell Receptor Pathway Inhibitors	20



## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	TMO ASSAY: Novel Biomarker for the Microbiome	20-21
	Computerized – Assisted Personalized Sedation Station.	21-22
	Relaxin for Acute Heart failure.	22-23
	Fecal Microbiota Transplantation.	23
	Preoperative Decision Support System.	24
	New Era in Hepatitis C Treatment.	24-26
	Responsive Neurostimulator for Intractable Epilepsy.	25-26
	Genome Guided Solid Tumor Diagnostic.	26
	Retinal Prosthesis.	27
4.3	World top 10 medical innovations 2015...	28
	Mobile stroke unit	28
	Dengue fever vaccine	28
	Painless blood testing	28
	New way of lower cholesterol	28
	Cancer drug that doesn't harm healthy tissues	29
	Immune booster for cancer patients	29
	Wireless cardiac pacemaker	29
	New medications for idiopathic pulmonary fibrosis	29
	Single-dose radiation therapy for breast cancer	29
	New drug for heart failure	30
	FDA approved drugs 2013	30-40
	FDA approved drugs 2014	40-50
	FDA approved drugs 2015	50-59
Chapter 5	Result and discussions	60-64
Chapter 6	Conclusion	66
Chapter 7	References.	68

# **CHAPTER 1**

## **INTRODUCTION**

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **Introduction:**

Medical innovation can be broadly defined as “new drugs, devices and clinical practices introduced over time into the provision of health care” <sup>[1]</sup>. Medical innovation does not only concern development of tangible products, such as drugs or machines, but also intangibles, such as clinical practices, institutional arrangements, treatment strategies, protocols and other medical artifacts. The last several decades have seen tremendous progress in the medical science, research, and technologies that can be used to prevent and fight many diseases. As a result, patient who acquire a medical disorder or disease are much more likely to survive the condition and live longer, healthier lives. However, a greater chance for survival does not come without complications.

Research advances have been employed to design more refined and narrowly targeted technology, methods, and pharmacological interventions to combat disease. Forty years ago, brain scans consisted of fixed image scans of moderate detail, useful for identifying gross abnormalities. Modern scanning technology offers substantially greater image clarity including three-dimensional rendering as well as the ability to monitor brain processes at work, both of which are helpful in identifying more subtle abnormalities of function. Treatments for childhood cancer consisting of powerful, broadly acting radiation, chemotherapy, and radical surgery have paved the way for increasingly refined treatments and surgery, which use computer-generated modeling and lasers that target the cancer cells directly with less collateral damage to surrounding healthy cells <sup>[2]</sup>.

Medications have also advanced significantly in past decades and now have much greater specificity of action and reduced side effects. Historically, psychopharmacological treatment for psychotic symptoms involved broad-acting dopamine antagonists such as chlorpromazine (Thorazine), which also induced marked side effects, including drowsiness, cardiovascular changes, neuromuscular reactions, dyskinesias, autonomic reactions, and so on. More recent antipsychotic medications, such as aripiprazole (Abilify), are highly targeted to specific dopamine receptors and offer partial antagonist (blocking) action while facilitating other necessary dopamine transmissions. This differential action is believed to moderate dopamine receptors involved in psychotic symptoms more effectively while decreasing the range and intensity of potential side effects.

Medications for controlling asthma have improved from bronchodilators, which minimized acute symptoms, to anti-inflammatory and anti-leukotriene medications and immunotherapy, which seek to control long-term effects and prevent the occurrence of acute asthma attacks. Medications to abate allergy symptoms have improved to include sustained release mechanisms with targeted antihistamine action, which minimize side effects such as drowsiness, enabling children to remain in school and alert (McCabe, 2008).

Outpatient services increased 29% from 1992 to 2000, while the rate of inpatient hospitalization and length of stay plateaued or decreased during the same time (Bernstein et al., 2003). This is

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

largely due to financial pressures of cost containment, as well as the scientific and technological advances that have allowed a shift from primary care in hospitals to outpatient settings, ambulatory settings, or home <sup>[2]</sup>.

### **Drug and FDA:**

Drug may be Natural or synthetic substance which (when taken into a living body) affects its functioning or structure, and is used in the diagnosis, mitigation, treatment, or prevention of a disease or relief of discomfort.

The Food and Drug Administration (FDA) is an agency within the U.S. Department of Health and Human Services. It consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations.

### **Responsibilities of FDA:**

- Protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective.
- Protecting the public from electronic product radiation.
- Assuring cosmetics and dietary supplements are safe and properly labeled.
- Regulating tobacco products.
- Advancing the public health by helping to speed product innovations.

FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.

### **How Drug should be approved by FDA:**

It takes on average 12 years and over US\$350 million to get a new drug from the laboratory onto the pharmacy shelf. Once a company develops a drug, it undergoes around three and a half years of laboratory testing, before an application is made to the U.S. Food and Drug Administration (FDA) to begin testing the drug in humans. Only one in 1000 of the compounds that enter laboratory testing will ever make it to human testing.

If the FDA gives the green light, the "investigative" drug will then enter three phases of clinical trials:

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

- Phase 1 uses 20-80 healthy volunteers to establish a drug's safety and profile. (about 1 year)
- Phase 2 employs 100-300 patient volunteers to assess the drug's effectiveness. (about 2 years)
- Phase 3 involves 1000-3000 patients in clinics and hospitals who are monitored carefully to determine effectiveness and identify adverse reactions. (about 3 years)

The company then submits an application (usually about 100,000 pages) to the FDA for approval, a process that can take up to two and a half years. After final approval, the drug becomes available for physicians to prescribe. At this stage, the drug company will continue to report cases of adverse reactions and other clinical data to the FDA.

The research-based pharmaceutical industry currently invests some US\$12.6 billion a year in new drug development. Historically, the drug development figure doubles every five years.

### **Various Types of Treatment Patterns in the World:**

- I. Medication therapy
- II. Surgery
- III. Transplantation
- IV. Artificial organ
- V. Vaccination
- VI. Chemoprophylaxis
- VII. Chemotherapy
- VIII. Drug rehabilitation
- IX. Epidemiologic treatment
- X. Behavior therapy
- XI. Psychotherapy

#### **I. Medication Therapy**

Medication Therapy is the act of giving drug or medicine to a patient. For example if you catch cold or fever, at first your doctor will give you medicine after that if it is in severe position, the doctor can diagnose a procedure like blood test, this is a secondary procedure. The first procedure is to give medicine to the patient.

Medication therapy management (MTM) is medical care provided by pharmacists whose aim is to optimize drug therapy and improve therapeutic outcomes for patients. Medication therapy management includes a broad range of professional activities, including but not limited to performing patient assessment and/or a comprehensive medication review, formulating a medication treatment plan, monitoring efficacy and safety of medication therapy, enhancing medication adherence through patient

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

empowerment and education, and documenting and communicating MTM services to prescribers in order to maintain comprehensive patient care. Medication therapy management includes five core components: a medication therapy review (MTR), personal medication record (PMR), medication-related action plan (MAP), intervention and/or referral, and documentation and follow-up. A MTR is a systematic process of collecting patient and medication-related information which occurs during the pharmacist-patient encounter. In addition, the MTR assists in the identification and prioritization of medication-related problems. During the MTM encounter, the pharmacist develops a PMR for use by the patient. The PMR includes all prescription and nonprescription products and requires updating as necessary. After assessing and identifying medication-related problems, the pharmacist develops a patient-specific MAP. The MAP is a list of self-management actions necessary to achieve the patient's specific health goals. In addition, the patient and pharmacist utilize the MAP to record actions and track progress towards health goals. During the MTM session, the pharmacist identifies medication-related problem(s) and determines appropriate intervention(s) for resolution. Often, the pharmacist collaborates with other health care professionals to resolve the identified problem(s). Following the patient encounter and/or intervention, the pharmacist must document his/her encounter and determine appropriate patient follow-up.<sup>[15]</sup>

### II. Surgery

Surgery is an ancient medical specialty that uses operative manual and instrumental techniques on a patient to investigate and/or treat a pathological condition such as disease or injury, to help improve bodily function or appearance or to repair unwanted ruptured areas. An act of performing surgery may be called a surgical procedure, operation, or simply surgery. In this context, the verb operate means to perform surgery<sup>[13]</sup>.

#### **Description of surgical procedure**<sup>[13]</sup>

- i. **Location**: At a hospital, modern surgery is often done in an operating theater using surgical instruments, an operating table for the patient, and other equipment.
- ii. **Patient safety**
- iii. **Preoperative care**: Prior to surgery, the patient is given a medical examination, receives certain pre-operative tests, and their physical status is rated according to the ASA physical status classification system. If these results are satisfactory, the patient signs a consent form and is given a surgical clearance. If the procedure is expected to result in significant blood loss, an autologous blood donation may be made some weeks prior to surgery. If the surgery involves the digestive system, the patient may be instructed to perform a bowel prep by drinking a solution of polyethylene glycol the night before the procedure.

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

- iv. **Staging for surgery:** In the pre-operative holding area, the patient changes out of his or her street clothes and is asked to confirm the details of his or her surgery. A set of vital signs are recorded, a peripheral IV line is placed, and pre-operative medications (antibiotics, sedatives, etc.) are given. When the patient enters the operating room, the skin surface to be operated on, called the operating field, is cleaned and prepared by applying an antiseptic such as chlorhexidine gluconate or povidone-iodine to reduce the possibility of infection. If hair is present at the surgical site, it is clipped off prior to prep application.
- v. **Surgery:** An incision is made to access the surgical site. Blood vessels may be clamped or cauterized to prevent bleeding, and retractors may be used to expose the site or keep the incision open. The approach to the surgical site may involve several layers of incision and dissection, as in abdominal surgery, where the incision must traverse skin, subcutaneous tissue, three layers of muscle and then peritoneum. In certain cases, bone may be cut to further access the interior of the body; for example, cutting the skull for brain surgery or cutting the sternum for thoracic (chest) surgery to open up the rib cage.
- vi. **Post-operative care:** After completion of surgery, the patient is transferred to the post anesthesia care unit and closely monitored. When the patient is judged to have recovered from the anesthesia, he/she is either transferred to a surgical ward elsewhere in the hospital or discharged home. During the post-operative period, the patient's general function is assessed, the outcome of the procedure is assessed, and the surgical site is checked for signs of infection. There are several risk factors associated with postoperative complications, such as immune deficiency and obesity. Obesity has long been considered a risk factor for adverse post-surgical outcomes.<sup>[10]</sup>

### III. Transplantation

Transplantation is the moving of an organ from one body to another or from a donor site to another location on the person's own body, to replace the recipient's damaged or absent organ. Organs and/or tissues that are transplanted within the same person's body are called autografts. Transplants that are recently performed between two subjects of the same species are called allografts. Allografts can either be from a living or cadaveric source.<sup>[14]</sup>

Organs that can be transplanted are the heart, kidneys, liver, lungs, pancreas, intestine, and thymus. Tissues include bones, tendons (both referred to as musculoskeletal grafts), cornea, skin, heart valves, nerves and veins.<sup>[11]</sup>

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **IV. Artificial Organs**

An artificial organ is a man-made device that is implanted or integrated into a human to replace a natural organ, for the purpose of restoring a specific function or a group of related functions so the patient may return to a normal life as soon as possible. The replaced function doesn't necessarily have to be related to life support, but often is.

Implied by this definition is the fact that the device must not be continuously tethered to a stationary power supply, or other stationary resources, such as filters or chemical processing units.<sup>[16]</sup>

### **Reasons<sup>[16]</sup>**

Reasons to construct and install an artificial organ, an extremely expensive process initially, which may entail many years of ongoing maintenance services not needed by a natural organ, might include:

- Life support to prevent imminent death while awaiting a transplant (e.g. artificial heart)
- Dramatic improvement of the patient's ability for self-care (e.g. artificial limb)
- Improvement of the patient's ability to interact socially (e.g. cochlear implant)
- Cosmetic restoration after cancer surgery or accident

### **Organs<sup>[16]</sup>**

- i. Brain
- ii. Cardia and pylorus valves
- iii. Corpora cavernosa
- iv. Ear
- v. Eye
- vi. Hear
- vii. Artificial Limbs
- viii. Liver
- ix. Lungs
- x. Pancreas
- xi. Bladder e.t.c

## **V. Vaccination**

Vaccination is the administration of antigenic material (a vaccine) to stimulate an individual's immune system to develop adaptive immunity to a pathogen. Vaccines can prevent or ameliorate morbidity from infection. When a sufficiently large percentage of a



## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

population has been vaccinated, this results in herd immunity. The effectiveness of vaccination has been widely studied and verified; for example, the influenza vaccine, the HPV vaccine, and the chicken pox vaccine. Vaccination is the most effective method of preventing infectious diseases; widespread immunity due to vaccination is largely responsible for the worldwide eradication of smallpox and the restriction of diseases such as polio, measles, and tetanus from much of the world.<sup>[17]</sup>

### **VI. Chemoprophylaxis**

Chemoprevention (also Chemoprophylaxis) refers to the administration of a medication for the purpose of preventing disease or infection. Antibiotics, for example, may be administered to patients with disorders of immune system function to prevent bacterial infections (particularly opportunistic infection). Antibiotics may also be administered to healthy individuals to limit the spread of an epidemic, or to patients who have repeated infections (such as urinary tract infections) to prevent recurrence. It may also refer to the administration of heparin to prevent deep venous thrombosis in hospitalized patients.

In some cases, chemoprophylaxis is initiated to prevent the spread of an existing infection in an individual to a new organ system, as when intrathecal chemotherapy is administered in patients with malignancy to prevent further infection.<sup>[15]</sup>

### **VII. Chemotherapy**

Chemotherapy (often abbreviated to chemo and sometimes CTX or CTx) is a category of cancer treatment that uses chemical substances, especially one or more anti-cancer drugs (chemotherapeutic agents) that are given as part of a standardized chemotherapy regimen. Chemotherapy may be given with a curative intent, or it may aim to prolong life or to reduce symptoms (palliative chemotherapy). Along with hormonal therapy and targeted therapy, it is one of the major categories of medical oncology (pharmacotherapy for cancer). These modalities are often used in conjunction with other cancer treatments, such as radiation therapy, surgery, and/or hyperthermia therapy. Chemotherapy is also used to treat other conditions, including AL amyloidosis, ankylosing spondylitis, multiple sclerosis, Crohn's disease, psoriasis, psoriatic arthritis, systemic lupus erythematosus, rheumatoid arthritis, and scleroderma.<sup>[16]</sup>

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **VIII. Drug rehabilitation**

Drug rehabilitation (often drug rehab or just rehab) is a term for the processes of medical or psychotherapeutic treatment, for dependency on psychoactive substances such as alcohol, prescription drugs, and street drugs such as cocaine, heroin or amphetamines. The general intent is to enable the patient to cease substance abuse, in order to avoid the psychological, legal, financial, social, and physical consequences that can be caused, especially by extreme abuse. Treatment includes medication for depression or other disorders, counseling by experts and sharing of experience with other addicts. Some rehab centers include meditation and spiritual wisdom in the treatment process. A few centers also treat gambling with the same techniques as are used in drug rehabilitation.<sup>[17]</sup>

### **IX. Epidemiologic treatment**

Epidemiologic treatment refers to antibiotics administered when a diagnosis is considered likely on clinical, laboratory, or epidemiologic grounds, but before the results of confirmatory laboratory tests are known. This treatment is justified on the grounds that the potential benefits of treating the patient outweigh the potential harm of not treating. This potential harm may affect the individual or the community.<sup>[18]</sup>

### **X. Behavior Therapy**

Behavior therapy is the systematic application of the principles of learning to the treatment of psychological disorders. Because the focus is on changing behavior—not on personality change or deep probing into the past—behavior therapy is relatively brief, lasting typically from a few weeks to a few months. Behavior therapists, like other therapists, seek to develop warm therapeutic relationships with clients, but they believe the special efficacy of behavior therapy derives from the learning-based techniques rather than from the nature of the therapeutic relationship.<sup>[19]</sup>

### **XI. Psychotherapy**

Psychotherapy is a systematic interaction between a client and a therapist that draws on psychological principles to help bring about changes in the client's behaviors, thoughts, and feelings. Psychotherapy is used to help clients overcome abnormal behavior, solve problems in living, or develop as individuals.<sup>[19]</sup>

## **CHAPTER 2**

# **SIGNIFICANCE OF THE STUDY**

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **Significance of the Study:**

- The knowledge of recent medical advances are gathered from this study.
- The knowledge of main focusing area of medical interest are known.
- Main medical research points are identified
- To know the date of approval of many drugs.
- The phases of approval of drugs and how they are approved can also be learned from this work.
- The significance of the top 10 medicines in the world can also be learned.

## **CHAPTER 3**

# **METHODOLOGY**

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **Methodology:**

The objective of the study was to identify recent medical advances and FDA approved drugs within last three years. Methodology used for this study was random and extensive survey of related literature, annual press release from different hospitals, clinics and healthcare organizations. Literatures were selected based on medical acceptance, authenticity, publishing journals. Secondary sources were relevant search of internet based information from various health related websites. Information were compiled based on their priority and acceptance on medical field. Data found from different sources were further analyzed represent and compare the newly FDA approved drugs and medical innovations.

## **CHAPTER 4**

# **FINDINGS OF THE STUDY**

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **Findings of the Study:**

### **4.1 World top 10 Medical Innovation: 2013<sup>[5]</sup>**

The year 2013 was chock-full of advances in healthcare. From diagnostic tools that fit in our pocket to a flurry of breakthroughs in HIV research, 2013 was an eventful year—and the stage is set for even greater leaps in 2014 and beyond. The Healthline team chose these innovations as some of 2013's most exciting. To receive consideration, nominated technologies had to meet the following criteria.

- i. The Innovation must have had significant impact and offer significant patient benefit in comparison to current practice. It must also have high user related functionality that improve health care delivery.
- ii. Nominated Innovation had to have high probability of commercial success
- iii. The Innovation must be in or exiting clinical trials and be available on the market sometime in 2013.
- iv. The Innovation must have significant human interest in its application or benefits and must have the ability to visualize human impact.

#### **I. Bariatric Surgery for Control of Diabetes:**

Exercise and diet alone are not effective for treating severe obesity or Type 2 diabetes. Once a person reaches 100 pounds or more above his or her ideal weight, losing the weight and keeping it off for many years almost never happens.

While the medications we have for diabetes are good, about half of the people who take them are not able to control their disease. This can often lead to heart attack, blindness, stroke, and kidney failure.

Surgery for obesity, often called bariatric surgery, shrinks the stomach into a small pouch and rearranges the digestive tract so that food enters the small intestine at a later point than usual.

Over the years, many doctors performing weight-loss operations found that the surgical procedure would rid patients of Type 2 diabetes, oftentimes before the patient left the hospital.



## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

Many diabetes experts now believe that weight-loss surgery should be offered much earlier as a reasonable treatment option for patients with poorly controlled diabetes —and not as a last resort.

### **II. Neuromodulation Device for Cluster and Migraine Headaches:**

The sphenopalatine ganglion (SPG) nerve bundle — located behind the bridge of the nose — has been a specific target for the treatment of severe headache pain for many years.

Researchers have invented an on-demand patient-controlled stimulator for the SPG nerve bundle. This miniaturized implantable neurostimulator, the size of an almond, is placed through a minimally invasive surgical incision in the upper gum above the second molar. The lead tip of the implant is placed at the SPG nerve bundle on the side of the face where headache pain is typically experienced by the patient. Whenever a patient feels a headache coming on, a remote control device is placed on the cheek and it delivers as needed stimulation to the SPG, blocking the headache pain in about five to 10 minutes.

In European testing, 68 percent of patients responded to neuromodulation therapy, achieving cluster attack pain relief, reduction in attack frequency, or both. Now already approved and available in Europe for the treatment of cluster headaches, the FDA has granted investigational use of the neurostimulation system for cluster headaches for use in the United States.

### **III. Mass Spectrometry for Bacterial Identification:**

Even in this age of advanced medical technology, identification of bacteria growing in culture can still require days or weeks.

However, clinical microbiology laboratories throughout the world are now implementing new mass spectrometry technology to provide rapid organism identification that is more accurate and less expensive than current biochemical methods.

Using one of the two MALDI-TOF mass spectrometry systems currently available in the United States provides more accurate identification of bacteria in minutes — rather than days.

Rapid organism identification now allows clinicians to prescribe the most appropriate treatment sooner and de-escalate therapy from broad-spectrum agents that drive antimicrobial resistance. At a time when bacterial infections account for a large proportion of people admitted to hospitals each year, quick and accurate detection of these microorganisms help guide appropriate patient treatment and improve outcomes is more critical than ever.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **IV. Drugs for Advanced Prostate Cancer:**

In the past two years, five new drugs have been approved for advanced prostate cancer: sipuleucel-T, denosumab, abiraterone, cabazitaxel, and enzalutamide. A sixth, radium-223 dichloride, is expected to be approved later this year.

Significant progress has been made in treating advanced prostate cancer, not only by greatly increasing patient survival, but also by halting the progress of this disease.

Many in the prostate cancer research community now believe that these drugs, and others coming from the prostate cancer therapeutic pipeline, will one day help make advanced prostate cancer a chronic disease that's successfully managed with a routine of daily medication, lifestyle modification, and regular checkups.

### **V. Hand-held Optical Scan for Melanoma:**

A new FDA-approved handheld office device assists dermatologists in identifying skin lesions that have characteristics of melanoma.

Without cutting the skin, the device—which uses imaging technology created by the military for guided missile navigation—is placed on the skin over the mole. Special lights of 10 specific wavelengths are shined on the skin, and the computerized system rapidly visualizes the micro-vessel structure of the lesion just below the skin's surface.

The device then uses sophisticated algorithms that objectively analyze the lesion. Next, the device compares the image findings it has just developed to a database of 10,000 archived images of melanoma and other skin diseases. In less than a minute, an assessment of the skin lesion is given and the dermatologist can then decide on possible next steps.

In a clinical trial of 1,300 patients, the largest study ever conducted in melanoma detection, the device detected 98% of the melanomas, while missing fewer than 2% of these early cancers.

### **VI. Femtosecond Laser Cataract Surgery:**

Unlike a surgical blade that cuts, a femtosecond laser separates tissue by ablating and cleaving it. The novel FDA-approved bladeless cataract procedure is now revolutionizing surgery by making it more predictable and accurate, allowing surgeons to make smaller, more precise incisions. It also requires less energy time inside the eye, causes less inflammation, and offers more stability when implanting a new lens.

A femtosecond is one quadrillionth of a second. This is the super-fast amount of time that numerous laser pulses of near infrared light are used by a surgeon in this new cataract procedure. The femtosecond laser helps make a perfect circular hole in the lens capsule, splits the lens into sections, and then softens and breaks up the cataract. The damaged lens is removed using ultrasound and an intraocular lens is then

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

implanted. The device has already been used successfully in ophthalmology, particularly for LASIK (Laser In-Situ Keratomileusis) refractive surgery.

### **VII. Ex Vivo Lung Perfusion:**

Experts believe that as many as 40 percent of previously rejected donor lungs may now be suitable for transplantation thanks to a new approach called ex vivo — outside the body — lung perfusion. This novel “lung washing” procedure can reverse lung injury in many donor organs deemed unsuitable and allow for transplantation.

In this new pioneering procedure, the damaged lungs are removed from a donor, placed in a bubble-like transparent chamber, and connected to a cardiopulmonary pump and a ventilator.

Over a four- to six-hour period, the lungs are then repaired and assessed. Special proprietary fluids are forced through the blood vessels and nutrients are used to re-nourish the lungs as they inflate and deflate as oxygen is pumped through. When necessary, targeted medications are introduced to clear infections. Once determined as being viable, they are ready for immediate transplantation.

Ex vivo lung perfusion — which is approved in Europe and Canada, and is now undergoing a major multicenter clinical trial in the United States — has the potential to significantly increase the number of available lungs as the reconditioning process is adopted, refined, and improved at multiple transplant centers. This increased availability of quality-tested donor lungs is going to make a huge difference to the 100,000 American patients with severe breathing problems who now wait on the lung transplant standby list.

### **VIII. Modular Devices for Treating Complex Aneurysms:**

Unfortunately, as many as 20 percent to 40 percent of people with aortic aneurysms have anatomies that are not suitable for the grafts that are currently marketed, nor are they candidates for the more demanding open surgical repair procedure.

However, thanks to a new innovative fenestrated stent graft system, surgeons can now treat patients with these complex aneurysms without having to take detailed measurements and then wait for weeks, sometimes months, for the customized endografts to be delivered.

The FDA recently approved a multi-center trial of the modular stent device for aneurysms that come close to the renal artery. The device incorporates individual branches to both renal arteries and the superior mesenteric artery.

Taken “off-the-shelf” by a surgeon, it can be used for both elective and urgent cases involving the renal arteries. The new modular stent graft system offers a significant reduction in morbidity and ICU stay, but more importantly, it allows an application of life-saving technology to high-risk patients who never could have been treated for their aneurysms.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **IX. Digital Breast Tomosynthesis (DBT):**

Tomosynthesis, or 3D mammography, is a diagnostic technology that was approved by the FDA in 2011. Breast tomosynthesis does not currently replace traditional two-dimensional mammography testing, but instead, it is performed along with the conventional mammogram to provide a more accurate view of the breast.

During the tomosynthesis portion of the exam, the x-ray arm of the machine makes a quick arc over the breast, taking dozens of images at a number of angles. Later combined to make a three-dimensional rendering of the entire breast, the images can be viewed by a radiologist at a computer workstation to check areas of concern. If cancers are found when they are small, treatment options are generally less traumatic and the chance for cure is greater.

What 3D technology offers doctors and mammography technicians is a much greater opportunity to discover small cancer cells obscured by surrounding tissue that may not be visible on standard mammograms. This is particularly the case in women with dense breasts, in which tumors often escape detection. Preliminary study results of 25,000 women reported a 47% increase in cancer detection when tomosynthesis was used.

3D mammography also reduces the much-feared callbacks for women. Due to a lack of diagnostic clarity, one in 10 women typically is asked to return for additional testing following a routine mammogram screening that has raised concern. However, in a recent study of 7,500 women, the recall rate of women screened with breast tomosynthesis and traditional mammography combined was 6.6% compared to 11.1% for traditional mammography alone.

### **X. Bee Venom Nanoparticles Attack HIV:**

Like the stingers from a thousand angry bees, a toxin isolated from bee venom is able to poke holes in the protective coating of HIV, the virus that causes AIDS. When attached to nanoparticles with a special bumper, the toxin melittin can kill the virus, while leaving healthy human cells intact. More work is needed, but the Washington University researchers say a vaginal cream with the bee venom nanoparticles could serve as a low-cost method of blocking infection.

“The implications are phenomenal—from preventing the spread of HIV where there's high rates of infection to treating existing infections,” said Tracy Stickler, Healthline's editorial director.

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### 4.2 World Top Medical Innovations of 2014.<sup>[6]</sup>

#### I. B Cell Receptor Pathway Inhibitors

Chemotherapy is a blunt instrument designed to indiscriminately kill rapidly dividing cells in the hope that the cancer cells die more and grow back less than healthy cells. That normal cells are routinely damaged in this destructive procedure accounts for the side effects and toxicity of traditional chemotherapy. Gleevec or Imatinib showed that if you can identify the biologic process contributing to a cancer, then drugs could be designed to interfere with that process, not only effectively treating the cancer, but also minimizing side effects.

In the ensuing years, cancer research has shifted to this new paradigm, resulting in many new therapies targeted to the cancer and not to normal cells. The improvements in survival, however, have been modest compared to what was seen with imatinib. The B-cell receptor pathway tightly controls the growth of the infection-fighting cells we call B-cells. When B-cells become cancerous, this pathway becomes unregulated and contributes to the malignant nature of the cells.<sup>[4]</sup>

However, this overactive pathway can be inhibited by novel drugs. In the last year, the results of clinical trials in humans conclusively showed that these new drugs are extremely effective at treating low-grade B-cell lymphomas and leukemias for a long time and with very few side effects. Ibrutinib targets **Bruton's tyrosine kinase (BTK)**, a protein essential for B-cell survival and proliferation. While it kills malignant B cells, ibrutinib has little effect on healthy T cells—unlike other lymphoma therapies. This leaves an important arm of the immune system largely intact, enabling patients to remain healthier during treatment. Many patients respond well to this novel B-cell receptor pathway inhibitor, which lacks many of the side effects of chemotherapy, and it frequently produces long-lasting remissions even in patients with high-risk genetic lesions. Results from a study published in the *The New England Journal of Medicine* in 2013 reported an overall response rate of 71% for patients with chronic lymphocytic leukemia (CLL) who were treated with ibrutinib tablets. At 26 months, the estimated progression-free survival rate was 75% and overall survival was 83%. Ibrutinib has also shown very promising results in the treatment of patients with other B-cell malignancies, including mantle cell lymphoma (MCL), a rare and aggressive B-cell subtype of non-Hodgkin lymphoma.

#### II. TMO ASSAY: Novel Biomarker for the Microbiome

There is a global hunt in progress using a variety of cardiovascular fingerprints scientists call them biomarkers that have been discovered or created to help identify the initiation, development, and ongoing cascade of damage caused by heart disease.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

Scientists have now discovered what may be an important new biomarker for heart disease that serves as an accurate screening tool for predicting future risks of heart attack, stroke, and death in persons not otherwise identified by traditional risk factors and blood tests. The novel biomarker is called TMAO, or **trimethylamine N-oxide**, and it's a microbial byproduct of intestinal bacteria.

TMAO is produced when intestinal bacteria digest the nutrient phosphatidylcholine, which is more commonly known as choline. This metabolite is thought to promote **atherosclerosis** by contributing to cholesterol metabolism in heart artery walls as well as in the liver and intestines. Major dietary sources of choline include **egg yolks, red meat, and dairy products**.

Tests of TMAO levels of more than 4,000 adults undergoing angiography over a three-year period recently revealed that TMAO levels are good indicators of who is at risk for serious heart disease and can also serve as a possible future treatment target. <sup>[4]</sup>

As reported in The New England Journal of Medicine (NEJM) in 2013, those people with the highest levels of TMAO had double the risk of death, nonfatal heart attack, or stroke compared to those with the lowest levels. heart disease is the number one killer of American adults and still remains. <sup>[7]</sup>

What this important NEJM study has confirmed is that assessing blood levels of TMAO generated by bacteria in the gut can serve as a powerful tool for predicting future cardiovascular risk, even for those people without known risk factors.

### **III. Computerized – Assisted Personalized Sedation Station.**

A colonoscopy is an exam that lets a gastroenterologist look closely at the inside of the entire colon and rectum for polyps, the small growths that over time can become cancerous. Using a colonoscope, a thin, flexible, hollow, lighted tube that has a tiny video camera on the end, the doctor sends pictures to a TV screen. The exam itself takes about 30 minutes. Patients are usually given light sedation to help them relax and sleep while the procedure is performed.

Colonoscopies are now the most expensive screening test that healthy Americans routinely undergo, but despite the cost more than 10 million Americans electing to have colonoscopies each year, according to the **Centers for Disease Control and Prevention**, and this adds more than \$10 billion in annual costs to the healthcare system.

According to a study in the Journal of the American Medical Association, 14% of people had an anesthesiologist or nurse anesthetist present during their procedures in 2003, but that number had jumped to 30% six years later. It's also been estimated that payments to anesthesiologists for colonoscopy sedation quadrupled between 2003 and 2009, and that eliminating anesthesiologist services could save more than \$1 billion a year.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

In order to deliver minimal-to-moderate sedation during a colonoscopy procedure without using the services of an anesthesiologist, a new computer-assisted personalized sedation device that delivers the prescription drug **propofol** for sedation via intravenous IV infusion was given premarket approval by the FDA in 2013. The novel technology is expected to empower healthcare facilities to more effectively use their limited resources to deliver greater value in the increasingly resource-constrained U.S. healthcare environment.<sup>[4]</sup>

The new sedation system is a first-of-a-kind device in the world that allows non-anesthesia professionals to administer the drug **propofol** during colonoscopy procedures as long as they have professional training and use the machine where there is immediate availability of an anesthesia professional.

The device can also be used for an **esophagogastroduodenoscopy** (EGD) procedure, which is an in-office test to examine the lining of the esophagus, stomach, and first part of the small intestine. A physician-led team performs the EGD with a small camera that is inserted through the mouth and down the esophagus while patient is sedated.

### **IV. Relaxin for Acute Heart failure.**

Heart failure is a debilitating and potentially life-threatening condition in which the heart is unable to pump enough blood to supply the body.

- Symptoms of fatigue.
- Shortness of breath.
- and fluid retention are
- Resulted by a weakened or stiffened heart, significantly diminishing its ability to fill normally or effectively distribute blood.

### **According to the American Heart Association**

- Approximately five million people experience heart failure in the United States.
- More than half a million new cases are diagnosed annually in this country.

Heart failure affects both quality of life and life-span. This debilitating ailment is now the most common diagnosis in Medicare patients and accounts for 55,000 deaths annually. Patients experiencing an acute heart failure episode have to be rushed to the hospital for treatment. Although it's a diagnosis that carries a poor prognosis, it's one that is improved and enhanced by medical and device therapy and, in limited cases, heart transplantation. A variety of drugs and devices are now used by doctors to help patients with heart failure feel better, but half of those hospitalized don't survive longer than five years.

Serelaxin, a synthetic version of the naturally occurring hormone human relaxin-2, which is associated with pregnancy, has proven that it can help treat patients with acute, decompensated heart failure episodes after being infused over a 48-hour period in the hospital.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

In women, relaxin helps loosen tissues in the reproductive organs and pelvic ligaments to help prepare for childbirth. The hormone also relaxes blood vessels, allowing them to expand. During pregnancy, this allows more blood to reach the placenta and kidneys without raising blood pressure. Serelaxin is a drug called a vasodilator. In people with heart failure, the chemically engineered form of relaxin increases blood flow throughout the body, which helps a poorly functioning heart to be more effective. <sup>[4]</sup>

Relaxin is also an anti-inflammatory. Inflammation associated with heart failure can damage the kidneys, liver, and heart, but serelaxin appears to help prevent this from occurring. A serelaxin study result reported a 38% reduction in death rates after six months in patients with acute heart failure, compared with those who received standard therapy

### **V. Fecal Microbiota Transplantation.**

The microbiota, or mix of microbes, in your intestines exists in a delicate state of balance. Sometimes, antibiotics used for treatment can undo that balance by killing both aggressive and friendly bacteria.

When this happens, hardy *C. diff* (*Clostridium difficile*) microbes live on often with disastrous results when they spread infection from person to person.

**Fecal Microbiota Transplantation**, also known as human stool transplants.

In this therapy doctors transfer a liquid suspension made from a healthy person's fecal matter into a sick person's colon. The goal is to restore bacterial balance and fight infections and diseases. This approach could become a primary therapy not only for treating deadly and difficult *C. diff* infection, but also for inflammatory bowel disease.

*Clostridium difficile* poses such high risks because of how it spreads, particularly in hospitals. It can be transmitted to hands, food, utensils, sheets, countertops and curtains as spores. When passed to another person, these spores lead to intestinal inflammation, diarrhea, nausea, vomiting and abdominal pain.

According to the U.S. Centers for Disease Control and Prevention, *C. diff* infections have increased to 500,000 cases each year in the United States. That includes 15,000 deaths annually.

Fecal transplantation might help bring those numbers down.



## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **VI. Preoperative Decision Support System.**

In the past, monitoring patients during surgery was relatively simple a finger on the pulse and a blood pressure cuff.

However, advances in anesthesia have increased the amount of information recorded during surgery. The anesthetic record is now one of the most detailed accounts in all of medicine. It's also highly complicated.

In order to meet the demands of modern surgery and improve the standard of care, a new anesthesia management system that combines the latest in computer technology and microelectronics is now available.

This innovative system electronically documents the care provided by an anesthesiologist, from pre-op to intra-op and recovery, producing a complete anesthesia record of events, drugs, and procedures. It's this real-time patient data acquisition that elevates the quality of clinical decision-making, patient surveillance, and physician oversight. Designed by anesthesiologists for anesthesiologists, this electronic anesthesia record and clinical guidance system enables anesthesia best practices to be carried out and helps to reduce the risk of anesthetic errors. The ability of this anesthesia information management system to collect data automatically enables anesthesiologists to reliably and continuously create an accurate record, regardless of other demands during surgery. In addition, it also builds a compliant, billable electronic anesthesia record while also supporting the clinical team managing the needs of the patient, whether a centenarian with multiple health issues or an infant who is eight weeks premature and struggling to thrive. <sup>[4]</sup>

The first piece of the new technology is an anesthesia information management and documentation system that gathers and records physiological patient data, including heart rate, blood pressure, and respiratory rate in real-time during an operation and display it on the screen.

### **VII. New Era in Hepatitis C Treatment.**

Hepatitis C infection, a common liver disease that affects an estimated four million people in the United States, is transmitted through exposure to infected blood (blood was not screened effectively for hepatitis C until 1992) or sexual contact with an infected person. The majority of people with the ailment don't realize that they have the disease because of a lack of symptoms.

Hepatitis C is typically diagnosed when abnormal liver enzymes are identified through a routine blood test or if the infection becomes severe. Seventy percent of patients with hepatitis C develop chronic disease and 30% may develop scarring of the liver and cirrhosis of the liver within 20 years of exposure to the virus. An additional 20% of these patients eventually develop liver cancer. About 15,000 deaths are linked to the disease in the United States each year.

Until 2011, there were no proven medicines for patients who didn't respond to traditional hepatitis C therapy. Two advanced drugs called hepatitis C protease inhibitors, Top 10 selections

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

from Cleveland Clinic in 2011, were the first drugs approved by the FDA in a decade. These medications fundamentally changed the treatment for hepatitis C for patients who had not responded to previous therapies—patients infected with genotype 1 disease.

The drugs belong to a class of medications called protease inhibitors, which work by blocking a key enzyme that viruses need in order to proliferate. When the drug telaprevir (Incivek) is added to standard treatments for hepatitis C, more than 70% of patients can expect sustained viral response (or viral cure) after taking the medication for 24 weeks.<sup>[4]</sup>

Study results with the second drug, boceprevir (Victrelis), showed that when combined with the drugs interferon and ribavirin, boceprevir cured the infections of about 66% of the patients who took the drugs for 48 weeks. While hepatitis C treatment has improved considerably, especially when compared to the 1990s, the news is even better now. Sofosbuvir, the first all-oral hepatitis C treatment, is moving through the final stages of FDA approval. What this direct-acting antiviral (DAA) drug has is the potential to improve what for many has been a very difficult treatment regimen that can take up to 48 weeks and requires injections of interferon, a drug that is difficult to tolerate.

More important, the drug can improve treatment response rates to 90% or higher in central group of patients.

### **VIII. Responsive Neurostimulator for Intractable Epilepsy.**

Epilepsy is a neurological condition that produces seizures brief disturbances in the normal electrical activity of the brain that affect various mental and physical functions.

Seizures happen when clusters of nerve cells in the brain signal abnormally, which may briefly alter a person's consciousness or movements. When a person has two or more unprovoked seizures, he or she is considered to have epilepsy.

#### **According to the Institute of Medicine.**

- epilepsy affects as many as 2.8 million Americans,
- while the ailment affects 65 million people worldwide, and after migraine, stroke.
- Alzheimer's disease it's the fourth most common neurological disorder in this country.
- Its prevalence is greater than cerebral palsy, multiple sclerosis, autism spectrum disorder, and Parkinson's disease combined,
- despite medication regimen, more than one million people continue to have seizures.
- About 30% of Americans have intractable epilepsy, which is a seizure disorder in which a patient's seizures fail to come under control with treatment. Also called "uncontrolled" or "refractory," intractable epilepsy interferes with a patient's quality of life and can destroy life as well.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

- Sudden unexpected death in epilepsy, or SUDEP, is a serious concern. SUDEP is a nonaccidental death in a person with epilepsy, who was otherwise in a usual state of health. In people with frequent epileptic seizures that are poorly controlled with medications, the death rate is approximately 1 in 150 per year. People who are not seizure free need to be careful about possible accidents during a seizure. Those with intractable epilepsy need to take caution while in water or near busy streets or railway platforms, and they're often required to surrender their driver's license. Epilepsy surgery is a possibility for some with intractable epilepsy, but many cannot have it due to the risks or because it's unlikely to be helpful. There is now another option. An implanted neurological device that can significantly reduce the frequency of epileptic seizures gained the unanimous backing of an FDA neurological device advisory panel in 2013. Surgically implanted under the skin, the small device records electrocorticographic (ECog) patterns through leads containing electrodes that are placed at the patient's seizure focus within the brain or else they rest on the brain.

### **IX. Genome Guided Solid Tumor Diagnostic.**

Too often, men and women hear the words "prostate cancer," "breast cancer," or "colorectal cancer" from their doctor and immediately think the worst.

However, many times the aggressive therapies patients are offered or that they demand are unnecessary. In some cases, very aggressive treatments can even do more harm than good.

New **Genomic based tests** make decisions about treatment smarter, easier and more reliable.

Genomics focuses on groups of genes and how they interact in cells, as well as the role they play in health and disease. Tests based on this growing science can analyze the genes in a person's tumor to predict how it will behave.

The goal of these tests to avoid aggressive treatment when it is not needed and save lives when it is needed.

In 2013, the U.S. Food and Drug Administration approved an innovative addition to this genomic toolbox. A new prostate cancer determines how aggressive cancer is based on the biology of a man's individual tumor.

The prostate cancer test triples the number of patients who can confidently consider "active surveillance." This treatment plan involves careful monitoring and avoids unnecessary treatment and side effects. The test also identifies a smaller number of patients with aggressive cancer who need immediate treatment.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **X. Retinal Prosthesis.**

In a healthy eye, the rods and cones of the retina are specialized cells that convert light into tiny electrochemical impulses that are sent via the optic nerve into the brain, where they are decoded into images.

However, if these delicate photoreceptors are ever damaged, the initial step in the process is disrupted and the visual system cannot transform light into images, leading to blindness.

Retinitis pigmentosa, or RP, is a group of rare inherited diseases that damage these light-sensitive cells. People with RP experience a gradual decline in their vision because photoreceptor cells—the rods and cones—of the retina slowly degenerate, causing a gradual loss of side and night vision and, eventually, central vision and color. Many patients become totally blind in both eyes.

More than 100,000 people in the U.S. and 1.5 million people worldwide have retinitis pigmentosa, a disease whose most devastating consequence is blindness. Most people with RP are legally blind by age 40.

Up until now, there has been no effective treatment for late-stage RP. But a new technology featuring a retinal prosthesis commonly dubbed the “bionic eye” changes everything.

This technology combines a surgically implanted retinal prosthesis, video-camera-enabled glasses, and a video processing unit that is worn at the waist or carried.

The new technology essentially replaces the degenerated cells in the retina and helps patients perceive patterns of light in the brain. People then learn to interpret these patterns of light — and thereby regain some visual function.<sup>[4]</sup>

The retinal implant does not restore complete vision. But it does allow people to detect light and dark in the environment and identify the location or movement of people and objects.

Results from a clinical study of 30 participants who received the “bionic eyes” reported that most were able to perform basic activities better with the prosthesis than without it. They could walk on a sidewalk without stepping off the curb; match black, grey, and white socks; and recognize large letters, words and sentences.

After two decades of development and testing and more than \$200 million in funding, the U.S. Food and Drug Administration approved the system in 2013. The retinal prosthesis is a game changer for sight-affecting diseases and a huge step forward for the thousands of people who previously had no other treatment options.

# **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

## **4.3 World Top Medical Innovations of 2015.<sup>[7]</sup>**

### **I. Mobile stroke unit**

Videoconferencing has made its way into ambulances, specifically for treating stroke victims on the go. Hospital stroke neurologists can interpret symptoms via a broadband video link and instruct an onboard paramedic, critical care nurse and CT technologist on treatment. This new technology should improve the speed of medical care, which is important as strokes quickly damage and kill brain cells.

### **II. Dengue fever vaccine**

The World Health Organization reports that about half of the world's population is now at risk for dengue fever, which up until now was preventable only by avoiding mosquito bites. The disease is a leading cause of death and illness in children in some countries. A new vaccine has been developed and tested, and is expected to be available in 2015.

### **III. Painless blood testing**

For those who hate large needles, a nearly painless way to sample blood will be a welcome relief. Plus, it will be cheaper and provide faster results than today's blood test. The new technology takes blood from your fingertip, and the Cleveland Clinic reports that over 100 tests can be performed on just one drop of blood.

### **IV. New way to lower cholesterol**

New self-injectable drugs called PCSK9 inhibitors have shown to be very effective in lowering cholesterol. These drugs may prove to be helpful for people with high LDL cholesterol who don't have good results with statins. The FDA is expected to approve the first PCSK9 in 2015.

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **V. Cancer drug that doesn't harm healthy tissue**

Although chemotherapy can save lives, it can be hard on the body and attack healthy cells as well as cancerous ones. A welcome breakthrough in the world of cancer treatment, antibody-drug conjugates can deliver targeted treatment without damaging healthy tissue.

### **VI. Immune booster for cancer patients**

Immune checkpoint inhibitors have been shown to prevent cancer cells from "hiding" from the immune system, allowing the body to more effectively fight these abnormal cells. Combined with chemotherapy and radiation treatment, the drugs have shown significant, long-term cancer remissions for patients with metastatic melanoma, one of the most deadly forms of cancer.

### **VII. Wireless cardiac pacemaker**

Until this point, wires have been a necessary component in pacemakers. A new wireless pacemaker about the size of a vitamin can now be implanted in the heart without surgery. Its lithium-ion battery is estimated to last about seven years.

### **VIII. New medications for idiopathic pulmonary fibrosis**

Idiopathic pulmonary fibrosis is a life-threatening disease that causes scarring in the lungs, leading to breathing difficulties and a shortage of oxygen in the brain and other organs. Life expectancy is only three to five years after diagnosis, but those numbers may change now that the FDA has approved two experimental drugs that slow the disease: pirfenidone and nintedanib.

### **IX. Single-dose radiation therapy for breast cancer**

The National Cancer Institute estimates that 40,000 women in the United States will die from breast cancer in 2014. The Cleveland Clinic cites multiple chemotherapy appointments, sometimes requiring the patient to travel long distances, as a hindrance to successful treatment. Intraoperative radiation therapy is a new solution. It treats a breast cancer tumor during surgery in a single dose, reducing time and cost spent on treatment.

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### X. New drug for heart failure

About 5.1 million people in the United States suffer from heart failure, according to the National Heart, Lung and Blood Institute. It is managed with a combination of drugs, but a new drug, angiotensin-receptor neprilysin inhibitor, has been granted fast-track status by the FDA because of its ability to cut the risk of dying from heart failure more effectively than current treatments.

### **FDA Approved Drugs of 2013<sup>[8]</sup>**

The following database contains a listing of drugs approved by the Food and Drug Administration (FDA) for sale. Drug information typically includes the drug name, approval status, indication of use, and the name of the company.

#### **Cardiology/Vascular Diseases**

S/N	Generic name	Company	Indication	Approval date
I.	<u>Adempas</u> ( <u>riociguat</u> )	Bayer Healthcare Pharmaceuticals	For the treatment of Chronic Thromboembolic Pulmonary Hypertension and Pulmonary Arterial Hypertension	Approved October 2013
II.	<u>Kynamro</u> ( <u>mipomersen sodium</u> )	Genzyme	For the treatment of homozygous familial hypercholesterolemia	Approved January 2013
III.	<u>Liptruzet</u> ( <u>ezetimibe and atorvastatin</u> )	Merck	For the treatment of hyoerlipidemia	Approved May 2013
IV.	<u>Nymalize</u> ( <u>nimodipine</u> )	Arbor Pharmaceuticals	For the reduction of incidence and severity of ischemic deficits following subarachnoid hemorrhage	Approved May 2013
V.	<u>Opsumit</u> ( <u>macitentan</u> )	Actelion Pharmaceuticals	For the treatment of pulmonary arterial hypertension	Approved October 2013
VI.	<u>Varithena</u> ( <u>polidocanol injectable foam</u> )	BTG plc	For the treatment of varicose veins	Approved November 2013

#### **Dermatology**

S/N	Generic name	Company	Indication	Approval date
i.	<u>Luzu (luliconazole)</u> <u>Cream 1%</u>	Valeant Pharmaceuticals	For the treatment of interdigitaltineapedis, tineacuris, and tineacorporis	November of 2013
ii.	<u>Mekinist</u>	GlaxoSmithKline	For the treatment of	Approved

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	<u>(trametinib)</u>		unresectable or metastatic melanoma with BRAF V600E or V600K mutations	May of 2013
iii.	<u>Mirvaso (brimonidine)</u>	Galderma Labs	For the treatment of facial erythema of rosacea	Approved August 2013
iv.	<u>Sitavig (acyclovir) buccal tablets</u>	BioAlliancePharma	For the treatment of recurrent herpes labialis in adults	Approved April 2013
v.	<u>Tafinlar (dabrafenib)</u>	GlaxoSmithKline	For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation	Approved May 2013
vi.	<u>Valchlor (mechlorethamine) gel</u>	Ceptaris Therapeutics	For the treatment of Stage IA/IB mycosisfungoides-type cutaneous T-cell lymphoma	Approved August 2013
vii.	<u>Varithena (polidocanol injectable foam)</u>	BTG plc	For the treatment of varicose veins	November 2013

### Devices

S/N	Generic name	Company	Indication	Approval date
i.	<u>BreoEllipta (fluticasone furoate and vilanterol inhalation powder)</u>	GlaxoSmithKline	For the treatment of chronic obstructive pulmonary disease	Approved May 2013

### Endocrinology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Brisdelle (low-dose paroxetine mesylate)</u>	Noven Pharmaceuticals	For the treatment of vasomotor symptoms of menopause	Approved July 2013
ii.	<u>Duavee (conjugated estrogens/bazedoxifene)</u>	Pfizer	For the treatment of vasomotor symptoms associated with menopause and postmenopausal osteoporosis	Approved October 2013
iii.	<u>Invokana (canagliflozin)</u>	Janssen Pharmaceuticals	For the treatment of type II diabetes mellitus	Approved April 2013
iv.	<u>Nesina (alogliptin)</u>	Takeda	; For the treatment of type II diabetes mellitus	Approved January 2013
v.	<u>Osphena (ospemifene)</u>	Shionogi	For the treatment of dyspareunia and vulvar and vaginal atrophy due to	Approved March 2013



## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

			menopause	
--	--	--	-----------	--

### Family Medicine

S/N	Generic name	Company	Indication	Approval date
i.	<u>AnoroEllipta (umeclidinium and vilanterol inhalation powder)</u>	GlaxoSmithKline	For the maintenance treatment of chronic obstructive pulmonary disease	Approved December of 2013
ii.	<u>BreoEllipta (fluticasone furoate and vilanterol inhalation powder)</u>	GlaxoSmithKline	For the treatment of chronic obstructive pulmonary disease	Approved May 2013
iii.	<u>Diclegis (doxylamine succinate + pyridoxine hydrochloride DR tablets)</u>	Duchesnay USA	For the treatment of nausea and vomiting of pregnancy	Approved April 2013
iv.	<u>Duavee (conjugated estrogens/bazedoxifene)</u>	Pfizer	For the treatment of vasomotor symptoms associated with menopause and postmenopausal osteoporosis	Approved October 2013
v.	<u>Flublok (seasonal influenza vaccine)</u>	Protein Sciences	For the active immunization against influenza virus subtypes A and type B	Approved January 2013
vi.	<u>Ilaris (canakinumab)</u>	Novartis	For the treatment of Systemic Juvenile Idiopathic Arthritis	Approved May 2013
vii.	<u>Invokana (canagliflozin)</u>	Janssen Pharmaceuticals	For the treatment of type II diabetes mellitus	Approved April 2013
viii.	<u>Liptruzet (ezetimibe and atorvastatin)</u>	Merck	For the treatment of hyperlipidemia	May 2013
ix.	<u>Nesina (alogliptin)</u>	Takeda	For the treatment of type II diabetes mellitus	Approved January 2013
x.	<u>Olysio (simeprevir)</u>	Janssen Therapeutics	For the treatment of hepatitis C	November of 2013

### Gastroenterology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Simponi (golimumab);</u>	Janssen Biotech	For the treatment of ulcerative colitis	Approved May 2013
ii.	<u>Stivarga (regorafenib)</u>	Bayer	For the treatment of gastrointestinal stromal tumor	Approved February 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

iii.	<u>Uceris</u> (budesonide)	Santarus	For the treatment of ulcerative colitis	Approved January 2013

### Genetic Disease

S/N	Generic name	Company	Indication	Approval date
i.	<u>Kineret, anakinra</u> ;	Swedish Orphan Biovitrum;	For the treatment of Cryopyrin-Associated Periodic Syndromes,	Approved January 2013
ii.	<u>Kynamro</u> (mipomersen sodium);	Genzyme;	For the treatment of homozygous familial hypercholesterolemia,	Approved January 2013
iii.	<u>Ravicti (glycerol phenylbutyrate)</u> ;	Hyperion Therapeutics;	For the treatment of pediatrics and adults with urea cycle disorders,	Approved February 2013
iv.	<u>Tretten(Coagulation Factor XIII A-Subunit [Recombinant])</u> ;	Novo Nordisk;	For the treatment of congenital factor XIII (FXIII) A-subunit deficiency,	Approved December of 2013

### Healthy Volunteers

S/N	Generic name	Company	Indication	Approval date
i.	Flublok (seasonal influenza vaccine);	Protein Sciences;	For the active immunization against influenza virus subtypes A and type B,	Approved January 2013

### Hematology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Gazyva</u> (obinutuzumab);	Genentech;	For the treatment of previously untreated chronic lymphocytic leukemia,	Approved October of 2013
ii.	<u>Imbruvica</u> (ibrutinib);	Pharmacyclics;	For the treatment of mantle cell lymphoma, Approved November of 2013	
iii.	<u>Injectafer (ferric carboxymaltose injection)</u> ;	Luitpold Pharmaceuticals;	For the treatment of iron deficiency anemia,	Approved July 2013
iv.	<u>Kcentra</u> (Prothrombin Complex Concentrate);	CSL Behring;	For the reversal of vitamin K antagonist therapy-induced coagulation factor deficiency,	Approved May 2013
v.	<u>Nymalize</u> (nimodipine);	Arbor Pharmaceuticals;	For the reduction of incidence and severity of ischemic deficits following subarachnoid hemorrhage,	Approved May 2013
vi.	<u>Pomalyst</u> (pomalidomide);	Celgene;	For the treatment of relapsed and refractory multiple	Approved February 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

			myeloma,	
vii.	<u>Ravicti (glycerol phenylbutyrate);</u>	Hyperion Therapeutics;	For the treatment of pediatrics and adults with urea cycle disorders,	Approved February 2013
viii.	<u>Revlimid (lenalidomide);</u>	Celgene;	For the treatment of mantle cell lymphoma, Approved June 2013	
ix.	<u>Rixubis (Coagulation Factor IX (Recombinant));</u>	Baxter International;	For the routine prophylaxis and control of hemophilia B,	Approved June 2013
x.	<u>Tretten (Coagulation Factor XIII A-Subunit [Recombinant]);</u>	Novo Nordisk;	For the treatment of congenital factor XIII (FXIII) A-subunit deficiency,	Approved December of 2013
xi.	<u>Valchlor (mechlorethamine) gel;</u>	Ceptaris Therapeutics;	For the treatment of Stage IA/IB mycosisfungoides-type cutaneous T-cell lymphoma,	Approved August 2013

### Hepatology (Liver, Pancreatic, Gall Bladder)

S/N	Generic name	Company	Indication	Approval date
i.	<u>Olysio (simeprevir);</u>	Janssen Therapeutics;	For the treatment of hepatitis C,	November of 2013
ii.	<u>Sovaldi (sofosbuvir);</u>	Gilead Sciences;	For the treatment of hepatitis C,	December of 2013

### Immunology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Flublok (seasonal influenza vaccine);</u>	Protein Sciences;	For the active immunization against influenza virus subtypes A and type B,	Approved January 2013
ii.	<u>Kineret, anakinra;</u>	Swedish Orphan Biovitrum;	For the treatment of Cryopyrin-Associated Periodic Syndromes,	Approved January 2013
iii.	<u>Simponi (golimumab);</u>	Janssen Biotech;	For the treatment of ulcerative colitis, Approved May 2013	
iv.	<u>Sitavig (acyclovir) buccal tablets;</u>	BioAlliancePharma;	For the treatment of recurrent herpes labialis in adults,	Approved April 2013
v.	<u>Tecfidera (dimethyl fumarate);</u>	Biogen Idec;	For the treatment of relapsing multiple sclerosis,	Approved March 2013
vi.	<u>Tivicay (dolutegravir);</u>	ViiV HealthCare;	For the treatment of HIV-1 in adults and children over 12 years of age,	Approved August 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

vii.	<u>VariZIG, Varicella Zoster Immune Globulin (Human);</u>	Cangene;	For the post-exposure prophylaxis of varicella zoster (chickenpox),	Approved January 2013
------	---	----------	---	-----------------------

### Infections and Infectious Diseases

S/N	Generic name	Company	Indication	Approval date
i.	<u>Flublok (seasonal influenza vaccine);</u>	Protein Sciences;	For the active immunization against influenza virus subtypes A and type B,	Approved January 2013
ii.	<u>Luzu (Iuliconazole) Cream 1%;</u>	Valeant Pharmaceuticals;	For the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis,	November of 2013
iii.	<u>Olysio (simeprevir);</u>	Janssen Therapeutics;	For the treatment of hepatitis C,	November of 2013
iv.	<u>Sitavig (acyclovir) buccal tablets;</u>	BioAlliancePharma;	For the treatment of recurrent herpes labialis in adults,	Approved April 2013
v.	<u>Sovaldi (sofosbuvir);</u>	Gilead Sciences;	For the treatment of hepatitis C,	December of 2013
vi.	<u>VariZIG, Varicella Zoster Immune Globulin (Human);</u>	Cangene;	For the post-exposure prophylaxis of varicella zoster (chickenpox),	Approved January 2013
vii.	<u>Vibativ (telavancin);</u>	Theravance;	For the treatment of hospital-acquired and ventilator-associated bacterial pneumonia caused by <i>staph aureus</i> ,	Approved June 2013

### Musculoskeletal

S/N	Generic name	Company	Indication	Approval date
i.	<u>Actemra (ocilizumab);</u>	Genentech;	For the treatment of Polyarticular Juvenile Idiopathic Arthritis,	Approved May 2013
ii.	<u>Duavee (conjugated estrogens/bazedoxifene)</u>	Pfizer;	For the treatment of vasomotor symptoms associated with menopause and postmenopausal osteoporosis,	Approved October 2013
iii.	<u>Ilaris (canakinumab);</u>	Novartis;	For the treatment of Systemic Juvenile Idiopathic Arthritis,	Approved May 2013
iv.	<u>Tecfidera (dimethyl fumarate);</u>	Biogen Idec;	For the treatment of relapsing multiple sclerosis,	Approved March 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Nephrology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Injectafer (ferric carboxymaltose injection);</u>	Luitpold Pharmaceuticals;	For the treatment of iron deficiency anemia,	Approved July 2013
ii.	<u>Procysbi (cysteaminebitartrate);</u>	Raptor Pharmaceuticals;	For the management of nephropathiccystinosis,	Approved May 2013

### Neurology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Aptiom (eslicarbazepine acetate);</u>	Sunovion Pharmaceuticals;	For the adjunctive treatment of partial-onset seizures,	Approved November 2013
ii.	<u>Fetzima (levomilnacipran);</u>	Forest Laboratories;	For the treatment of major depressive disorder,	Approved July 2013
iii.	<u>Nymalize (nimodipine);</u>	Arbor Pharmaceuticals;	For the reduction of incidence and severity of ischemic deficits following subarachnoid hemorrhage,	Approved May 2013
iv.	<u>Trokendi XR (topiramate);</u>	Supernus Pharmaceuticals;	For the treatment of partial onset, tonic-clonic and Lennox-Gastaut Syndrome seizures,	Approved August 2013
v.	<u>Zohydro ER (hydrocodone bitartrate) Extended-Release Capsules;</u>	Zogenix;	For the management of severe pain,	Approved October 2013
vi.	<u>Zubsolv (buprenorphine and naloxone);</u>	Orexo AB;	For the maintenance treatment of opioid dependence,	Approved July 2013

### Nutrition and Weight Loss

S/N	Generic name	Company	Indication	Approval date
i.	<u>Nesina (alogliptin);</u>	Takeda;	For the treatment of type II diabetes mellitus,	Approved January 2013

### Obstetrics/Gynecology (Women's Health)

S/N	Generic name	Company	Indication	Approval date
i.	<u>Brisdelle (low-dose paroxetine mesylate);</u>	Noven Pharmaceuticals	For the treatment of vasomotor symptoms of menopause,	Approved July 2013
ii.	<u>Diclegis (doxylamine succinate + pyridoxine hydrochloride DR tablets);</u>	Duchesnay USA;	For the treatment of nausea and vomiting of pregnancy,	Approved April 2013
iii.	<u>Duavee (conjugated estrogens/bazedoxifene);</u>	Pfizer;	For the treatment of vasomotor symptoms	Approved October 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

			associated with menopause and postmenopausal osteoporosis,	
iv.	<u>Kadcyla (ado-trastuzumabemtansine);</u>	Genentech;	For the treatment of HER2-positive metastatic breast cancer,	Approved February 2013
v.	<u>Lo Minastrin, (norethindrone acetate, ethinyl estradiol, ferrous fumarate);</u>	Warner Chilcott;	For the prevention of pregnancy,	Approved July 2013
vi.	<u>Osphena (ospemifene);</u>	Shionogi;	For the treatment of dyspareunia and vulvar and vaginal atrophy due to menopause,	Approved March 2013
vii.	(levonorgestrel/ethinyl estradiol and ethinylestradiol);	Teva Pharmaceutical;	For the prevention of conception	, Approved April 2013

### Oncology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Gazyva (obinutuzumab);</u>	Genentech;	For the treatment of previously untreated chronic lymphocytic leukemia,	Approved October of 2013
ii.	<u>Gilotrif (afatinib);</u>	BoehringerIngelheim;	For the treatment of metastatic non-small cell lung cancer with EGFR mutations,	Approved July 2013
iii.	<u>Imbruvica (ibrutinib);</u>	Pharmacyclics;	For the treatment of mantle cell lymphoma,	Approved November of 2013
iv.	<u>Kadcyla (ado-trastuzumabemtansine);</u>	Genentech;	For the treatment of HER2-positive metastatic breast cancer,	Approved February 2013
v.	<u>Mekinist (trametinib);</u>	GlaxoSmithKline;	For the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations,	Approved May of 2013
vi.	<u>Pomalyst (pomalidomide);</u>	Celgene;	For the treatment of relapsed and refractory multiple myeloma,	Approved Feb 2013
vii.	<u>Revlimid (lenalidomide);</u>	Celgene;	For the treatment of mantle cell lymphoma,	Approved June 2013
viii.	<u>Stivarga (regorafenib);</u>	Bayer;	For the treatment of gastrointestinal stromal tumor,	Approved Feb 2013
ix.	<u>Tafinlar(dabrafenib);</u>	GlaxoSmithKline;	For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation,	Approved May 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

x.	<u>Valchlor (mechlorethamine) gel</u> ;	Ceptaris Therapeutics;	For the treatment of Stage IA/IB mycosisfungoides-type cutaneous T-cell lymphoma,	Approved August 2013
xi.	<u>Xgeva (denosumab)</u> ;	Amgen;	For the treatment of giant cell tumor of bone, Approved June 2013	
xii.	<u>Xofigo (radium Ra 223 dichloride)</u> ;	Bayer Healthcare Pharmaceuticals;	For the treatment of prostate cancer with bone metastases,	Approved May 2013

### Orthopedics/Orthopedic Surgery

S/N	Generic name	Company	Indication	Approval date
i.	<u>Xgeva (denosumab)</u> ;	Amgen;	For the treatment of giant cell tumor of bone,	Approved June 2013

### Pediatrics/Neonatology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Actemra (ocilizumab)</u> ;	Genentech;	For the treatment of Polyarticular Juvenile Idiopathic Arthritis,	Approved May 2013
ii.	<u>Ilaris (canakinumab)</u> ;	Novartis;	For the treatment of Systemic Juvenile Idiopathic Arthritis,	Approved May 2013
iii.	<u>Kineret, anakinra</u> ;	Swedish Orphan Biovitrum;	For the treatment of Cryopyrin-Associated Periodic Syndromes,	Approved January 2013
iv.	<u>Kynamro (mipomersen sodium)</u> ;	Genzyme;	For the treatment of homozygous familial hypercholesterolemia,	Approved January 2013
v.	<u>Ravicti (glycerol phenylbutyrate)</u> ;	Hyperion Therapeutics;	For the treatment of pediatrics and adults with urea cycle disorders,	Approved February 2013
vi.	<u>Tivicay (dolutegravir)</u> ;	ViiV HealthCare;	For the treatment of HIV-1 in adults and children over 12 years of age,	Approved August 2013
vii.	<u>Trokendi XR (topiramate)</u> ;	Supernus Pharmaceuticals;	For the treatment of partial onset, tonic-clonic and Lennox-Gastaut Syndrome seizures,	Approved August 2013

### Pharmacology/Toxicology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Kcentra (Prothrombin Complex Concentrate)</u> ;	CSL Behring;	For the reversal of vitamin K antagonist therapy-induced coagulation factor deficiency,	Approved May 2013

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Psychiatry/Psychology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Brintellix</u> ( <u>vortioxetine</u> );	Takeda Pharmaceuticals USA;	For the treatment of Major Depressive Disorder,	Approved October 2013
ii.	<u>Fetzima</u> ( <u>levomilnacipran</u> );	Forest Laboratories;	For the treatment of major depressive disorder,	Approved July 2013
iii.	<u>Zubsolv</u> ( <u>buprenorphine and naloxone</u> );	Orexo AB;	For the maintenance treatment of opioid dependence,	Approved July 2013

### Pulmonary/Respiratory Diseases

S/N	Generic name	Company	Indication	Approval date
i.	<u>Adempas (riociguat)</u> ;	Bayer Healthcare Pharmaceuticals;	For the treatment of Chronic Thromboembolic Pulmonary Hypertension and Pulmonary Arterial Hypertension,	Approved October 2013
ii.	<u>AnoroEllipta(umeclidinium and vilanterol inhalation powder)</u> ;	GlaxoSmithKline;	For the maintenance treatment of chronic obstructive pulmonary disease,	Approved December of 2013
iii.	<u>BreoEllipta (fluticasone furoate and vilanterol inhalation powder)</u> ;	GlaxoSmithKline;	For the treatment of chronic obstructive pulmonary disease,	Approved May 2013
iv.	<u>Opsumit (macitentan)</u> ;	Actelion Pharmaceuticals;	For the treatment of pulmonary arterial hypertension,	Approved October 2013
v.	<u>Vibativ (telavancin)</u> ;	Theravance;	For the treatment of hospital-acquired and ventilator-associated bacterial pneumonia caused by <i>staph aureus</i> ,	Approved June 2013

### Rheumatology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Actemra</u> ( <u>ocilizumab</u> );	Genentech;	For the treatment of PolyarticularJuvenile Idiopathic Arthritis,	Approved May 2013
ii.	<u>Ilaris</u> ( <u>canakinumab</u> );	Novartis;	For the treatment of Systemic Juvenile Idiopathic Arthritis,	Approved May 2013



## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Trauma (Emergency, Injury, Surgery)

S/N	Generic name	Company	Indication	Approval date
i.	<u>Kcentra</u> ( <u>Prothrombin Complex Concentrate</u> );	CSL Behring;	For the reversal of vitamin K antagonist therapy-induced coagulation factor deficiency,	Approved May 2013

### Urology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Xiaflex (collagenase clostridium histolyticum)</u> ;	Auxilium;	For the treatment of Peyronie's disease,	Approved December of 2013
ii.	<u>Xofigo (radium Ra 223 dichloride)</u> ;	Bayer Healthcare Pharmaceuticals;	For the treatment of prostate cancer with bone metastases,	Approved May 2013

### Vaccines

S/N	Generic name	Company	Indication	Approval date
i.	<u>Flublok (seasonal influenza vaccine)</u> ;	Protein Sciences;	For the active immunization against influenza virus subtypes A and type B,	Approved January 2013
ii.	<u>VariZIG, Varicella Zoster Immune Globulin (Human)</u> ;	Cangene;	For the post-exposure prophylaxis of varicella zoster (chickenpox),	Approved January 2013

## FDA Approves Drugs 2014.<sup>[8]</sup>

### Cardiology/Vascular disease

SL	Generic name	Brand name	Company	Indication	Approval date
i.	omega-3-carboxylic acids	<b>Epanova</b>	AstraZeneca	For the treatment of severe hypertriglyceridemia	May 2014
ii.	vorapaxar	<b>Zontivity</b>	Merck	For the reduction of thrombotic cardiovascular events	May 2014

### Dermatological Disease

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	( <b>dalbavancin</b> )	Dalvance	Durata therapeutics.	For the treatment of acute bacterial skin and skin structure infections	May 2014
ii.	<u>efinaconazole</u>	Jublia 10% topical gel	Valeant Pharmaceuticals	For the treatment of onychomycosis of	Approved

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

				the toenails,	June 2014
iii.	<u>tedizolid phosphate</u>	Sivextro	Cubist Pharmaceuticals	For the treatment of acute bacterial skin and skin structure infections,	Approved June 2014

### Endocrinology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Insulin human	Afrezzainhalatiti on powder	mannkind	For the treatment of diabetic melitus.	June 2014
ii.	Testosterone undecanoate	Aveed injection	Endo Pharmaceuticals	For the treatment of hypogonadism,	Approved March 2014
iii. iv.	dapagliflozin	farxiga	Bristo-meyerssquibb	For the treatment of type II diabetes,	January of 2014
v. vi.	Testosterone	Natesto nasal gel	Trimel Pharmaceuticals	For the treatment of deficiency or absence of endogenous testosterone,	Approved May 2014
vii. viii.	Albiglutide	Tanzeum	GlaxoSmithKline	For the treatment of typeII diabetes mellitus,	Approved April 2014
ix. x.	testosterone	Vogelxo gel	Upsher-Smith;	For males with a deficiency or absence of endogenous testosterone,	Approved June 2014

### Family Medicine<sup>[5]</sup>

SL No:	Generic name	Brand name	Company	Indication	Approval date
i. ii.	insulin human Inhalation Powder	Afrezza	Mannkind;	For the treatment of diabetes mellitus,	Approved June 2014
iii. iv.	Coagulation Factor IX (Recombinant), Fc Fusion Protein];	Alprolix	Biogen Idec	For the treatment of hemophilia B	Approved March 2014
v.	buprenorphine	Bunavail	BioDelivery	For the maintenance	Approved

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	and naloxone		Sciences;	treatment of opioid dependence	June 2014
vi.	naltrexone HCl and bupropion HCl;	Contrave	Takeda Pharmaceuticals U.S.A.;	For chronic weight management	September 2014
vii. viii.	dalbavancin	Dalvance	Durata	Therapeutics; For the treatment of acute bacterial skin and skin structure infections,	Approved May 2014
ix.	diclofenac sodium	Dyloject Injection	Hospira	For the management of mild, moderate or severe pain,	Approved December 2014
x.	(Timothy Grass Pollen Allergen Extract)	Grastek	Merck	For the treatment of grass pollen-induced allergic rhinitis	, Approved April 2014
xi.	(metreleptin for injection)	Myalept	Bristol-Myers Squibb	For the treatment of congenital or acquired generalized lipodystrophy,	Approved February of 2014
xii.	(droxidopa);	Northera	Chelsea Therapeutics;	For the treatment of neurogenic orthostatic hypotension	, Approved February 2014
xiii.	(Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass Mixed Pollens Allergen Extract);	Oralair	Greer Labs;	For the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis,	Approved April 2014
xiv.	Topiramate	Qudexy XR	Upsher-Smith Laboratories;	For the treatment of partial onset and primary generalized tonic-clonic seizures and Lennox-Gastaut Syndrome,	Approved March 2014
xv.	(Short Ragweed Pollen	Ragwitek	Merck;	For the treatment of short ragweed pollen-	Approved April 2014

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	Allergen Extract)			induced allergic rhinitis,	
--	-------------------	--	--	----------------------------	--

### Gastroenterology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	(netupitant and palonosetron);	Akynzeo	Helsinn	For the prevention of chemotherapy-induced nausea and vomiting,	Approved October 2014
ii.	(ramucirumab);	Cyramza	Eli Lilly	For the treatment of gastric cancer,	Approved April 2014
iii.	vedolizumab)	Entyvio	MilleniumPharmaceuticals	For the treatment of adults with ulcerative colitis and Crohn's disease	, Approved May of 2014
iv.	ceftolozane + tazobactam	Zerbaxa	CubistPharmaceuticals	For the treatment of complicated intra-abdominal and urinary tract infections,	Approved December 2014

### Genetic Disease

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Coagulation Factor IX Recombinant, Fc Fusion Protein	Alprolix	Biogen Idec;	For the treatment of hemophilia B,	Approved March 2014
ii.	eliglustat;	Cerdelga	Genzyme; 4	For the treatment of certain adult patients with Gaucher disease type 1,	Approved August 201
iii.	topiramate	Qudexy XR	Upsher-Smith Laboratories	For the treatment of partial onset and primary generalized tonic-clonic seizures and Lennox-Gastaut Syndrome	Approved March 2014
iv.	elosulfasealfa	Vimizim	BioMarin;	For, the treatment of Mucopolysaccharidosis type IVA	Approved February 2014

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Hematology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Belinostat	Beleodaq	Spectrum Pharmaceuticals;	For the treatment of relapsed or refractory peripheral T-cell lymphoma,	Approved July 2014
ii.	<u>Antihemophilic Factor (Recombinant), Fc Fusion Protein</u>	Eloctate	Biogen IDEC.;	For the treatment of hemophillia A,	Approved June 2014
iii.	ibrutinib	Imbruvica	Pharmacyclics;	For the treatment of chronic lymphocytic leukemia,	Approved February 2014
iv.	Antihemophilic Factor (Recombinant), Porcine Sequence	Obizur	Baxter	; For the treatment of acquired hemophilia A,	Approved October 2014
v.	vorapaxar	Zontivity	Merck	For the reduction of thrombotic cardiovascular events,	Approved May 2014

### Immunology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	vedolizumab	Entyvio	Millenium Pharmaceuticals;	For the treatment of adults with ulcerative colitis and Crohn's disease,	Approved May of 2014
ii.	umeclidinium inhalation powder	incrusEllipta	GlaxoSmithKline	For the treatment of chronic obstructive pulmonary disease,	Approved May 2014
iii.	apremilast	Otezla	Celgene	For the treatment of adults with active psoriatic arthritis,	Approved March 2014
iv.	Immune	HyQvia	Baxter	For the treatment of	Approved

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase			Primary Immunodeficiency,	September 2014
--	--	--	--	---------------------------	----------------

### **Infections and Infectious Diseases**

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	tavaborole	Kerydin	Anacor	For the treatment of onychomycosis of the toenails,	Approved July 2014
ii.	ledipasvir and sofosbuvir	Harvoni	Gilead	For the treatment of hepatitis C	October 2014
iii.	dalbavancin	Dalvance	Durata Therapeutics	For the treatment of acute bacterial skin and skin structure infections,	Approved May 2014
iv.	oritavancin	Orbactiv	The Medicines Company	For the treatment of acute bacterial skin and skin structure infections	Approved August 2014
v.	peramivir injection	Rapivab	Biocryst	For the treatment of acute uncomplicated influenza in adults,	Approved December 2014
vi.	abacavir, dolutegravir, and lamivudine	Triumeq	ViiV HealthCare;	For the treatment of HIV-1,	Approved August 2014

### **Musculoskeletal**

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	alemtuzumab	Lemtrada	Genzyme	For the treatment of relapsing multiple sclerosis,	Approved November 2014
ii.	apremilast	Otezla	Celgene	For the treatment of adults with active psoriatic arthritis,	Approved March 2014
iii.	elosulfasealfa	Vimizim	BioMarin	For the treatment of Mucopolysaccharidosis type IVA,	Approved February 2014

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Nephrology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Ferric citrate	Auryxia	KeryxBiopharma	For the treatment of hyperphosphatemia in patients with chronic kidney disease,	Approved September 2014
ii.	ledipasvir and sofosbuvir	Harvoni	Gilead	For the treatment of hepatitis C	Approved October 2014
iii.	ombitasvir, paritaprevir, ritonavir and dasabuvir	ViekiraPaktablets	Abbvie	For the treatment of genotype 1 chronic hepatitis C virus,	Approved December 2014

### Neurology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	suvorexant	Belsomra	Merck	For the treatment of insomnia,	Approved August 2014
ii.	(diclofenac sodium)	Dyloject <b>Injection</b>	Hospira	For the management of mild, moderate or severe pain	Approved December 2014
iii.	droxidopa	Northera	Chelsea Therapeutics;	For the treatment of neurogenic orthostatic hypotension,	Approved February 2014

### Nutrition and Weight Loss

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	naltrexone HCl and bupropion HCl	Contrave	Takeda Pharmaceuticals U.S.A.;	For chronic weight management	Approved September 2014
ii.	liraglutide [rDNA origin] injection	Saxenda	Novo Nordisk	For chronic weight management	Approved December 2014

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

iii.	albiglutide,	Tanzeum	GlaxoSmith Kline	For the treatment of type II diabetes mellitus	Approved April 2014
------	--------------	---------	------------------	--	---------------------

### Obstetrics/Gynecology (Women's Health)

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Olaparib	<u>Lynparza</u>	AstraZeneca	For the treatment of previously treated BRCA mutated advanced ovarian cancer,	Approved December 2014
ii.	Metronidazol	<u>Metronidazole 1.3% Vaginal Gel</u>	Actavis, Inc.;	For the treatment of bacterial vaginosis,	Approved April 2014

### Oncology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Netupitant and palonosetron	Akynzeo	Helsinn	For the prevention of chemotherapy-induced nausea and vomiting	Approved October 2014
ii.	Belinostat	Beleodaq	Spectrum Pharmaceuticals	For the treatment of relapsed or refractory peripheral T-cell lymphoma,	Approved July 2014
iii.	Ramucirumab	Cyramza	Eli Lilly	For the treatment of gastric cancer	Approved April 2014
iv.	Ibrutinib)	Imbruvica	Pharmacyclics	For the treatment of chronic lymphocytic leukemia,	Approved February 2014
v.	Ceritinib	Zykadia	Novartis	For the treatment of ALK+ metastatic non-small cell lung cancer,	Approved April 2014

### Ophthalmology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Tasimelteon	Hetlioz	Pharmaceuticals	Vanda For the treatment of non-24-hour sleep-wake disorder in the totally blind	January 2014
ii.	Phenylephrine	Omidria	Omeros;	For use during eye	Approved



## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	and ketorolac injection			surgery to prevent intraoperative miosis and reduce post-operative pain,	June 2014
--	-------------------------	--	--	--	-----------

### Orthopedics/Orthopedic Surgery

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Apremilast	Otezla	Celgene	For the treatment of adults with active psoriatic arthritis,	Approved March 2014

### Otolaryngology (Ear, Nose, Throat)

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass Mixed Pollens Allergen Extract	Oralair	Greer Labs	For the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis	Approved April 2014
ii.	Timothy Grass Pollen Allergen Extract	Grastek	Merck	For the treatment of grass pollen-induced allergic rhinitis,	Approved April 2014
iii.	Short Ragweed Pollen Allergen Extract)	Ragwitek	Merck	For the treatment of short ragweed pollen-induced allergic rhinitis,	Approved April 2014
iv.	<u>finafloxacinotic suspension</u>	Xtoro0.3%	Alcon	; For the treatment of acute otitis externa,	Approved December 2014

### Pharmacology/Toxicology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Netupitant and	<u>Akynzeo</u>	Helsinn	For the prevention	Approved

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	palonosetron			of chemotherapy-induced nausea and vomiting,	October 2014
ii.	Buprenorphine and naloxone	<u>Bunavail</u>	BioDelivery Sciences	For the maintenance treatment of opioid dependence,	Approved June 2014

### Rheumatology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	Apremilast	Otezla	Celgene	For the treatment of adults with active psoriatic arthritis,	Approved March 2014

### Pulmonary/Respiratory Diseases

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	fluticasone furoate inhalation powder	ArnuityE llipta	GlaxoSmithKline	For the treatment of asthma,	Approved August 2014
ii.	pirfenidone	Esbriet	nterMunel	For the treatment of idiopathic pulmonary fibrosis ,	Approved October 2014
iii.	Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass Mixed Pollens Allergen Extract	Oralair	Greer Labs	For the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis,	Approved April 2014
iv.	Short Ragweed Pollen Allergen Extract	Ragwitek	Merck	For the treatment of short ragweed pollen-induced allergic rhinitis,	Approved April 2014
v.	Nintedanib	Ofev	BoehringerIngelheim	For the treatment of idiopathic pulmonary fibrosis ,	Approved October 2014

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Sleep

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	<b>tasimelteon</b>	Hetlioz	Vanda Pharmaceuticals	For the treatment of non-24-hour sleep-wake disorder in the totally blind,	January 2014

### Urology

SL No:	Generic name	Brand name	Company	Indication	Approval date
i.	<u>ceftolozane + tazobactam</u>	Zerbaxa	Cubist Pharmaceuticals	For the treatment of complicated intra-abdominal and urinary tract infections,	Approved December 2014

## FDA Approved Drugs of 2015<sup>[9]</sup>

### **Cardiology/Vascular Diseases**

S/N	Generic name	Company	Indication	Approval date
i.	<u>Corlanor (ivabradine);</u>	Amgen;	For the treatment of chronic heart failure,	Approved April 2015
ii.	<u>Entresto (sacubitril and valsartan);</u>	Novartis;	For the treatment of chronic heart failure,	Approved July 2015
iii.	<u>Kanuma (sebelipasealfa);</u>	Alexion;	For the treatment of Lysosomal Acid Lipase (LAL) deficiency,	Approved December 2015
iv.	<u>Kengreal (cangrelor) ;</u>	The Medicines Company;	For reducing periprocedural thrombotic events,	Approved June 2015
v.	<u>Praluent (alirocumab);</u>	Sanofi Aventis;	For the treatment of heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease,	Approved July 2015
vi.	<u>Prestalia (perindopril arginine and amlodipine besylate);</u>	Symplmed Pharmaceuticals;	For the treatment of hypertension,	Approved January 2015
vii.	<u>Repatha (evolocumab) ;</u>	Amgen;	For the treatment of high cholesterol,	Approved August 2015
viii.	<u>Savaysa (edoxaban);</u>	Daiichi Sankyo;	For the treatment of deep vein thrombosis, pulmonary	Approved January 2015

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

			embolism and risk of stroke and embolism due to atrial fibrillation,	
ix.	<u>Uptravi (selexipag);</u>	Actelion Pharmaceuticals;	For the treatment of pulmonary arterial hypertension,	Approved December 2015

### Dermatology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Cosentyx (secukinumab);</u>	Novartis;	For the treatment of plaque psoriasis,	Approved January 2015
ii.	<u>Cotellic (cobimetinib);</u>	Genentech;	For the treatment of BRAF V600E or V600K melanoma,	Approved November 2015
iii.	<u>Enstilar (calcipotriene and betamethasone dipropionate);</u>	LEO Pharmaceuticals;	For the treatment of psoriasis,	Approved October 2015
iv.	<u>Imlygic (talimogenelaherparep vec);</u>	Amgen;	For the treatment of unresectable recurrent melanoma,	Approved October 2015
v.	<u>Kybella (deoxycholic acid);</u>	KytheraBiopharma;	For the treatment of submental fat, Approved April 2015	
vi.	<u>Odomzo (sonidegib);</u>	Novartis; For the treatment of locally advanced basal cell carcinoma,	July 2015	

### Endocrinology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Addyi (flibanserin);</u>	Sprout Pharmaceuticals;	For the treatment of premenopausal women with generalized hypoactive sexual desire disorder,	Approved August 2015
ii.	<u>Natpara (parathyroid hormone);</u>	NPS Pharmaceuticals;	For the control hypocalcemia in patients with hypoparathyroidism,	Approved January 2015
iii.	<u>Synjardy (empagliflozin and metformin hydrochloride);</u>	BoehringerIngelheim;	For the treatment of type II diabetes,	Approved August 2015
iv.	<u>Tresiba (insulin degludec injection);</u>	Novo Nordisk;	For glycemic control in adults with diabetes mellitus,	Approved September 2015

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Family Medicine

S/N	Generic name	Company	Indication	Approval date
i.	<u>Cosentyx (secukinumab);</u>	Novartis;	For the treatment of plaque psoriasis,	Approved January 2015
ii.	<u>Cresemba (isavuconazonium sulfate);</u>	Astellas;	For the treatment of invasive aspergillosis and invasive mucormycosis,	Approved March 2015
iii.	<u>Enstilar (calcipotriene and betamethasone dipropionate);</u>	LEO Pharmaceuticals;	For the treatment of psoriasis,	Approved October 2015
iv.	<u>Kybella (deoxycholic acid);</u>	KytheraBiopharma;	For the treatment of submental fat, Approved April 2015	
v.	<u>Otiprio (ciprofloxacin otic suspension);</u>	Otonomy;	For the treatment of pediatrics with bilateral otitis media with effusion undergoing tympanostomy tube placement,	Approved December 2015
vi.	<u>Savaysa (edoxaban);</u>	Daiichi Sankyo;	For the treatment of deep vein thrombosis, pulmonary embolism and risk of stroke and embolism due to atrial fibrillation,	Approved January 2015
vii.	<u>Viberzi (eluxadoline);</u>	Actavis;	For the treatment of irritable bowel syndrome with diarrhea,	Approved May 2015
viii.	<u>Xifaxan (rifaximin);</u>	Salix Pharmaceuticals;	For the treatment of irritable bowel syndrome with diarrhea ,	Approved May 2015

### Gastroenterology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Avycaz (ceftazidime-avibactam);</u>	Actavis;	For the treatment of complicated intra-abdominal and urinary tract infections,	Approved February 2015
ii.	<u>Cholbam (cholic acid);</u>	Asklepion Pharmaceuticals;	For the treatment of bile acid synthesis and peroxisomal disorders,	Approved March 2015
iii.	<u>Lonsurf (trifluridine and tipiracil);</u>	Taiho Oncology;	For the treatment of metastatic colorectal cancer ,	Approved September 2015
iv.	<u>Onivyde (irinotecan liposome injection);</u>	Merrimack;	For the treatment of metastatic pancreatic cancer following gemcitabine-	Approved October 2015

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

			based therapy,	
v.	<u>Varubi (rolapitant);</u>	Tesaro;	For the prevention of delayed nausea and vomiting associated with chemotherapy,	Approved September 2015
vi.	<u>Viberzi (eluxadoline);</u>	Actavis;	For the treatment of irritable bowel syndrome with diarrhea,	Approved May 2015
vii.	<u>Xifaxan (rifaximin);</u>	Salix Pharmaceuticals;	For the treatment of irritable bowel syndrome with diarrhea ,	Approved May 2015

### Genetic Disease

S/N	Generic name	Company	Indication	Approval date
i.	<u>Kanuma (sebelipasealfa);</u>	Alexion;	For the treatment of Lysosomal Acid Lipase (LAL) deficiency,	Approved December 2015
ii.	<u>Strensiq (asfotasealfa);</u>	Alexion;	For the treatment of hypophosphatasia,	Approved October 2015
iii.	<u>Xuriden (uridine triacetate);</u>	Wellstat Therapeutics;	For the treatment of hereditary oroticaciduria,	Approved September 2015

### Hematology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Darzalex (daratumumab);</u>	Janssen Biotech;	For the treatment of multiple myeloma,	Approved November 2015
ii.	<u>Farydak (panobinostat);</u>	Novartis;	For the treatment of multiple myeloma,	Approved February 2015
iii.	<u>Natpara (parathyroid hormone) ;</u>	NPS Pharmaceuticals;	For the control hypocalcemia in patients with hypoparathyroidism,	Approved January 2015
iv.	<u>Nuwiq(recombinant Factor VIII);</u>	Octapharma;	For the prophylaxis and treatment of hemophilia A,	Approved September 2015
v.	<u>Praxbind (idarucizumab);</u>	Boehringer Ingelheim;	For the reversal of the anticoagulant effects of dabigatran,	Approved October 2015
vi.	<u>Veltassa (patiromer);</u>	Relypsa;	For the treatment of hyperkalemia,	Approved October 2015

### Hepatology (Liver, Pancreatic, Gall Bladder)

S/N	Generic name	Company	Indication	Approval date
i.	<u>Cholbam (cholic acid);</u>	Asklepiion Pharmaceuticals;	For the treatment of bile acid synthesis and peroxisomal disorders,	Approved March 2015
ii.	<u>Daklinza (daclatasvir) ;</u>	Bristol-Myers Squibb;	For the treatment of chronic HCV genotype 3,	Approved July 2015
iii.	<u>Technivie,</u>	Abbvie;	For the treatment of chronic	Approved July

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	<u>(ombitasvir, paritaprevir and ritonavir);</u>		HCV genotype 4,	2015
--	--	--	-----------------	------

### Immunology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Cosentyx (secukinumab);</u>	Novartis;	For the treatment of plaque psoriasis,	Approved January 2015
ii.	<u>Envarsus XR (tacrolimus extended-release);</u>	Veloxis;	For the prophylaxis of organ rejection in kidney transplant patients ,	Approved July 2015
iii.	<u>Evotaz (atazanavir and cobicistat) ;</u>	Bristol-Myers Squibb;	For the treatment of HIV-1 infection,	Approved January 2015
iv.	<u>Genvoya (cobicistat, emtricitabine, and tenofovirafenamide)</u>	Gilead Sciences;	For the treatment of HIV-1 infection,	Approved November 2015
v.	<u>Prezcobix (darunavir and cobicistat);</u>	Janssen;	For the treatment of HIV-1 infection,	Approved January 2015

### Infections and Infectious Diseases

S/N	Generic name	Company	Indication	Approval date
i.	<u>Avycaz (ceftazidime-avibactam);</u>	Actavis;	For the treatment of complicated intra-abdominal and urinary tract infections,	Approved February 2015
ii.	<u>Bexsero (Meningococcal Group B Vaccine);</u>	Novartis;	For the treatment of invasive meningococcal disease caused by serogroup B,	Approved January 2015
iii.	<u>Cresemba (isavuconazonium sulfate) ;</u>	Astellas;	For the treatment of invasive aspergillosis and invasive mucormycosis,	Approved March 2015
iv.	<u>Daklinza (daclatasvir) ;</u>	Bristol-Myers Squibb;	For the treatment of chronic HCV genotype 3,	Approved July 2015
v.	<u>Evotaz (atazanavir and cobicistat) ;</u>	Bristol-Myers Squibb;	For the treatment of HIV-1 infection,	Approved January 2015
vi.	<u>Fluad (trivalent influenza vaccine);</u>	Seqirus;	For the prevention of influenza A and B,	Approved November 2015
vii.	<u>Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovirafenamide);</u>	Gilead Sciences;	For the treatment of HIV-1 infection,	Approved November 2015
viii.	<u>Prezcobix (darunavir and cobicistat);</u>	Janssen;	For the treatment of HIV-1 infection,	Approved January 2015
ix.	<u>Technivie, (ombitasvir,</u>	Abbvie;	For the treatment of chronic HCV genotype 4,	Approved July 2015

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	<u>paritaprevir and ritonavir</u> );			
--	--------------------------------------	--	--	--

### Musculoskeletal

S/N	Generic name	Company	Indication	Approval date
i.	<u>Vivlodex (meloxicam)</u>	Iroko Pharmaceuticals;	For the management of osteoarthritis pain,	Approved October 2015

### Nephrology

S/N	Generic name	Company	Indication	Approval date
i.	Envarsus XR (tacrolimus extended-release);	Veloxis;	For the prophylaxis of organ rejection in kidney transplant patients ,	Approved July 2015
ii.	<u>Zurampic (lesinurad)</u> ;	AstraZeneca;	For the treatment of hyperuricemia associated with gout ,	Approved December 2015

### Neurology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Aristada (aripiprazole lauroxil) extended-release injectable</u> ;	Alkermes;	For the treatment of schizophrenia,	Approved October 2015
ii.	<u>Belbuca (buprenorphine)</u> ;	Endo Pharmaceuticals;	For the management of severe pain, Approved October 2015	
iii.	<u>Duopa (carbidopa and levodopa) enteral suspension</u> ;	Abbvie;	For the treatment of motor fluctuations in patients with advanced Parkinson's disease,	Approved January 2015
iv.	<u>Rytary (carbidopa and levodopa) extended-release capsules</u> ;	Impax Labs;	For the treatment of Parkinson's disease,	Approved January 2015
v.	<u>Vivlodex (meloxicam)</u> ;	Iroko Pharmaceuticals;	For the management of osteoarthritis pain,	Approved October 2015
vi.	<u>Vraylar (cariprazine)</u> ;	Allergan;	For the treatment of schizophrenia and bipolar disorder,	Approved September 2015

### Obstetrics/Gynecology (Women's Health)

S/N	Generic name	Company	Indication	Approval date
i.	<u>Addyi (flibanserin)</u> ;	Sprout Pharmaceuticals;	For the treatment of premenopausal women with generalized hypoactive sexual desire disorder,	Approved August 2015
ii.	<u>Ibrance (palbociclib)</u> ;	Pfizer;	For the treatment of ER-positive, HER2-negative breast cancer,	Approved February 2015



## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Oncology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Alecensa</u> ( <u>alectinib</u> );	Roche;	For the treatment of ALK-positive, metastatic non-small cell lung cancer ,	Approved December 2015
ii.	<u>Cotellic</u> ( <u>cobimetinib</u> ) ;	Genentech;	For the treatment of BRAF V600E or V600K melanoma,	Approved November 2015
iii.	<u>Darzalex</u> ( <u>daratumumab</u> );	Janssen Biotech;	For the treatment of multiple myeloma, Approved November 2015	
iv.	<u>Empliciti</u> ( <u>elotuzumab</u> );	Bristol-Myers Squibb;	For the treatment of patients with multiple myeloma who have received prior therapies,	Approved November 2015
v.	<u>Farydak</u> ( <u>panobinostat</u> );	Novartis;	For the treatment of multiple myeloma,	Approved February 2015
vi.	<u>Ibrance</u> ( <u>palbociclib</u> );	Pfizer;	For the treatment of ER-positive, HER2-negative breast cancer,	Approved February 2015
vii.	<u>Imlygic</u> ( <u>talimogenelaparepvec</u> ) ;	Amgen;	For the treatment of unresectable recurrent melanoma,	Approved October 2015
viii.	<u>Lenvima</u> ( <u>lenvatinib</u> );	Eisai;	For the treatment of thyroid cancer,	Approved February 2015
ix.	<u>Lonsurf</u> ( <u>trifluridine and tipiracil</u> );	Taiho Oncology;	For the treatment of metastatic colorectal cancer ,	Approved September 2015
x.	<u>Ninlaro</u> ( <u>ixazomib</u> );	Millennium Pharmaceuticals;	For the treatment of multiple myeloma,	Approved November 2015
xi.	<u>Odomzo</u> ( <u>sonidegib</u> );	Novartis;	For the treatment of locally advanced basal cell carcinoma,	July 2015
xii.	<u>Onivyde</u> ( <u>irinotecan liposome injection</u> );	Merrimack;	For the treatment of metastatic pancreatic cancer following gemcitabine-based therapy,	Approved October 2015
xiii.	<u>Opdivo</u> ( <u>nivolumab</u> );	Bristol-Myers Squibb;	For the treatment of metastatic squamous non-small cell lung cancer,	Approved March 2015
xiv.	<u>Portrazza</u> ( <u>necitumumab</u> )	Eli Lilly;	For the treatment of metastatic squamous non-small cell lung	Approved November

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	;		cancer,	2015
xv.	<u>Tagrisso(osime rtinib);</u>	AstraZeneca;	For the treatment of EGFR T790M mutation positive non-small cell lung cancer ,	Approved November 2015
xvi.	<u>Unituxin (dinutuximab);</u>	United Therapeutics;	For the treatment of pediatrics with high-risk neuroblastoma,	Approved March 2015
xvii.	<u>Varubi (rolapitant);</u>	Tesaro;	For the prevention of delayed nausea and vomiting associated with chemotherapy,	Approved September 2015
xviii.	<u>Yondelis (trabectedin);</u>	Janssen;	For the treatment of liposarcoma or leiomyosarcoma,	Approved October 2015

### Orthopedics/Orthopedic Surgery

S/N	Generic name	Company	Indication	Approval date
i.	<u>Strensiq (asfotasealfa);</u>	Alexion;	For the treatment of hypophosphatasia,	Approved October 2015

### Otolaryngology (Ear, Nose, Throat)

S/N	Generic name	Company	Indication	Approval date
i.	<u>Otiprio (ciprofloxacin otic suspension);</u>	Otonomy;	For the treatment of pediatrics with bilateral otitis media with effusion undergoing tympanostomy tube placement,	Approved December 2015

### Pediatrics/Neonatology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Bexsero (Meningococcal Group B Vaccine);</u>	Novartis;	For the treatment of invasive meningococcal disease caused by serogroup B,	Approved January 2015
ii.	<u>Cholbam (cholic acid);</u>	Asklepion Pharmaceuticals;	For the treatment of bile acid synthesis and peroxisomal disorders,	Approved March 2015
iii.	<u>Kanuma (sebelipasealfa);</u>	Alexion;	For the treatment of Lysosomal Acid Lipase (LAL) deficiency,	Approved December 2015
iv.	<u>Orkambi (lumacaftor and ivacaftor);</u>	Vertex Pharmaceuticals;	For the treatment of cystic fibrosis,	Approved July 2015
v.	<u>Otiprio (ciprofloxacin otic suspension);</u>	Otonomy;	For the treatment of pediatrics with bilateral otitis media with effusion undergoing tympanostomy tube placement,	Approved December 2015
vi.	<u>Strensiq (asfotasealfa);</u>	Alexion;	For the treatment of hypophosphatasia,	Approved October 2015
vii.	<u>Unituxin (dinutuximab);</u>	United Therapeutics;	For the treatment of pediatrics with high-risk neuroblastoma,	Approved March 2015

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### Pharmacology/Toxicology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Bridion</u> (sugammadex);	Merck;	For the reversal of neuromuscular blockade induced by rocuronium and vecuronium in adults undergoing surgery,	Approved December 2015
ii.	<u>Vistogard</u> (uridine triacetate);	BTG;	For the emergency treatment of patients with a fluorouracil or capecitabine overdose,	Approved December 2015

### Psychiatry/Psychology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Aristada</u> (aripiprazole lauroxil) extended-release injectable;	Alkermes;	For the treatment of schizophrenia,	Approved October 2015
ii.	<u>Rexulti</u> (brexpiprazole);	Otsuka;	For the treatment of depression and schizophrenia,	Approved July 2015
iii.	<u>Vraylar</u> (cariprazine);	Allergan;	For the treatment of schizophrenia and bipolar disorder,	Approved September 2015

### Pulmonary/Respiratory Diseases

S/N	Generic name	Company	Indication	Approval date
i.	<u>Alecensa</u> (alectinib);	Roche;	For the treatment of ALK-positive, metastatic non-small cell lung cancer ,	Approved December 2015
ii.	<u>Nucala</u> (mepolizumab);	GlaxoSmithKline;	For the treatment of severe asthma with an eosinophilic phenotype,	Approved November 2015
iii.	<u>Opdivo</u> (nivolumab);	Bristol-Myers Squibb;	For the treatment of metastatic squamous non-small cell lung cancer,	Approved March 2015
iv.	<u>Orkambi</u> (lumacaftor and ivacaftor);	Vertex Pharmaceuticals;	For the treatment of cystic fibrosis,	Approved July 2015
v.	<u>Portrazza</u> (necitumumab) ;	Eli Lilly;	For the treatment of metastatic squamous non-small cell lung cancer,	Approved November 2015
vi.	<u>StioltoRespimat</u> (tiotropium bromide and olodaterol) ;	BoehringerIngelheim;	For the maintenance of chronic obstructive pulmonary disease,	Approved May 2015
vii.	<u>Tagrisso</u> (osimertinib);	AstraZeneca;	For the treatment of EGFR T790M mutation positive non-small cell lung cancer ,	Approved November 2015
viii.	<u>UtibronNeohaler</u>	Novartis;	For the long term,	Approved

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

	(indacaterol and glycopyrrolate);		maintenance treatment of airflow obstruction in patients with COPD,	October 2015
--	-----------------------------------	--	---	--------------

### Urology

S/N	Generic name	Company	Indication	Approval date
i.	<u>Avycaz</u> (ceftazidime-avibactam);	Actavis;	For the treatment of complicated intra-abdominal and urinary tract infections,	Approved February 2015
ii.	<u>Xuriden</u> (uridine triacetate);	Wellstat Therapeutics;	For the treatment of hereditary oroticaciduria,	Approved September 2015

### Vaccines

S/N	Generic name	Company	Indication	Approval date
i.	Bexsero (Meningococcal Group B Vaccine);	Novartis;	For the treatment of invasive meningococcal disease caused by serogroup B,	Approved January 2015

# **CHAPTER 5**

## **RESULT AND DISCUSSION**

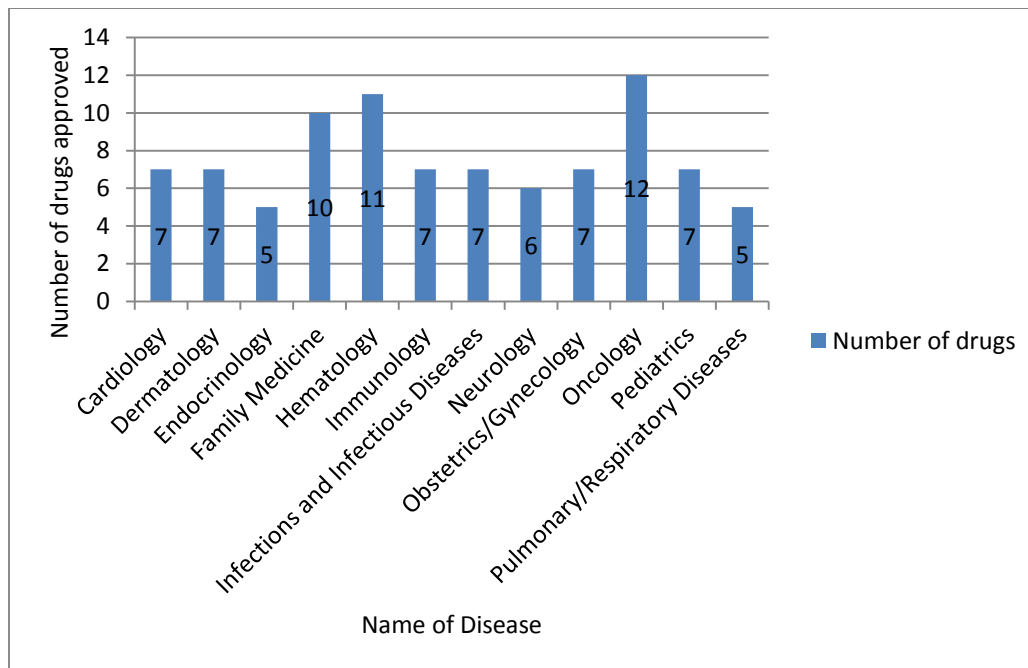
## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### **Result and Discussion:**

Table-1: Comprehensive list of drugs that are approved in 2013 in maximum amount<sup>[5]</sup>.

Sl. No.	Name of Diseases	Number of drugs approved
I.	Cardiology	7
II.	Dermatology	7
III.	Endocrinology	5
IV.	Family Medicine	10
V.	Hematology	11
VI.	Immunology	7
VII.	Infections and Infectious Diseases	7
VIII.	Neurology	6
IX.	Obstetrics/Gynecology	7
X.	Oncology	12
XI.	Pediatrics	7
XII.	Pulmonary/Respiratory Diseases	5

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

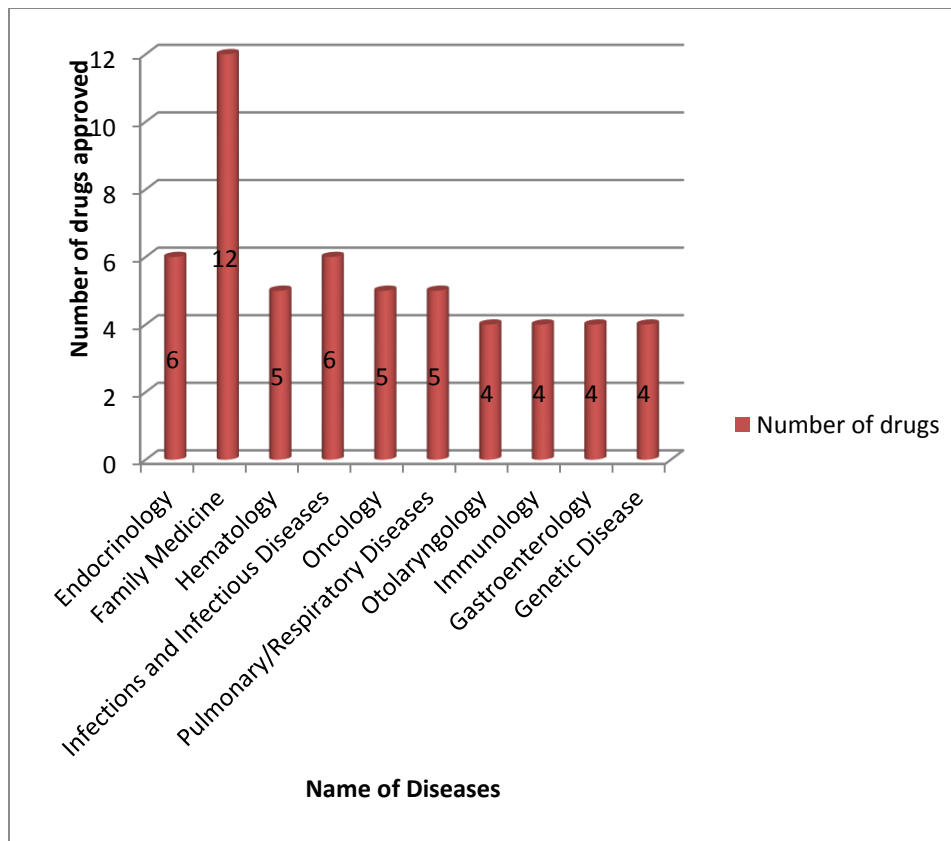


**Fig- 1: Comprehensive list of drugs that are approved in 2013 in maximum amount**

Table-2: Comprehensive list of drugs that are approved in 2014 in maximum amount<sup>[5]</sup>.

Sl. No.	Name of Diseases	Number of drugs approved
I.	Endocrinology	6
II.	Family Medicine	12
III.	Hematology	5
IV.	Infections and Infectious Diseases	6
V.	Oncology	5
VI.	Pulmonary/Respiratory Diseases	5
VII.	Otolaryngology	4
VIII.	Immunology	4
IX.	Gastroenterology	4
X.	Genetic Disease	4

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015



**Fig-2: Comprehensive list of drugs that are approved in 2014 in maximum amount**

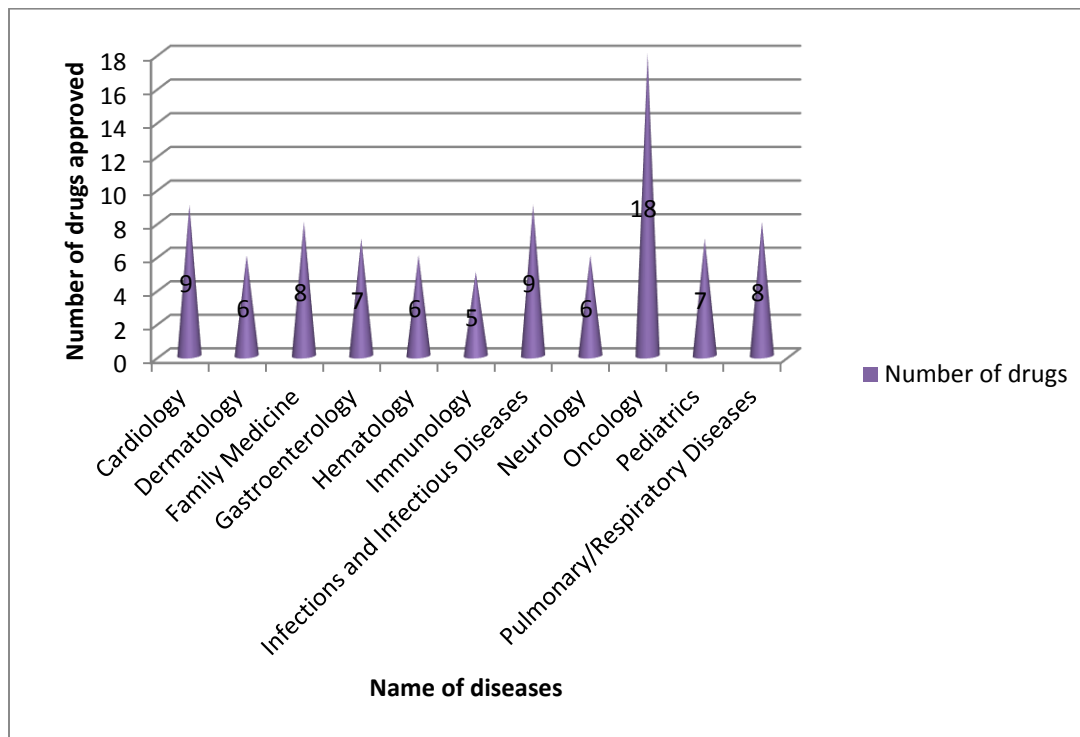
**Table-3: Comprehensive list of drugs that are approved in 2015 in maximum amount<sup>[5]</sup>.**

Sl. No.	Name of Diseases	Number of drugs approved
I.	Cardiology	9
II.	Dermatology	6
III.	Family Medicine	8
IV.	Gastroenterology	7
V.	Hematology	6
VI.	Immunology	5
VII.	Infections and Infectious Diseases	9
VIII.	Neurology	6
IX.	Oncology	18
X.	Pediatrics	7



## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

XI.	Pulmonary/Respiratory Diseases	8
-----	--------------------------------	---



**Fig-3: Comprehensive list of drugs that are approved in 2015 in maximum amount**

# **CHAPTER 6**

# **CONCLUSION**

## **WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015**

### **Conclusion:**

Medical innovations utilize many forms of knowledge and take the form of complex learning processes that span sectors, institutions and geographical and disciplinary boundaries. Different medical problems such as particular illnesses or therapies, devices etc. have been investigated in an evolutionary fashion; looking into how medical problems get formulated and solved over time, through the complex and dynamic interplay of different actors. The main actors in medical innovations – small and large firms, hospitals, universities, doctors and patients and the government - play specific roles, but collaboration across them is important.

As seen from above, many Significant and intricate life---saving developments were developed in these three years, and even more medical advancements are underway and nearing completion today. Technology has had a significant influence on the healthcare industry and its impact on medical operations, as well as medical capabilities, will continue to grow. It is important further to examine how advances in medical science and medical treatment strategies have affected the life of general people.

# **CHAPTER 7**

# **REFERENCES**

## WORLD'S TOP 10 MEDICAL INNOVATIONS & FDA APPROVED DRUGS LIST OF 2013 to 2015

### References:

1. Consoli, D. and A. Mina (2009). "An evolutionary perspective on health innovation systems." *Journal of Evolutionary Economics* **19**(2): 297-319.
2. *Paul C. McCabe and Steven R. Shaw*; *Advances in Health Care and Medical Science*, Book chapter-1, pp 1-5.
3. <http://www.webmd.com/10-most-important-drugs>
4. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1119266/>
5. Drug index by: Md Al-amin, world top 10 medical innovation 2013, page 712-734.
6. [http://innovations.clevelandclinic.org/App\\_Themes/MedicalInnovation/documents/topten2014/CC-BROCHURE-Top-10-2014-131010\\_0500](http://innovations.clevelandclinic.org/App_Themes/MedicalInnovation/documents/topten2014/CC-BROCHURE-Top-10-2014-131010_0500)
7. [http://innovations.clevelandclinic.org/App\\_Themes/MedicalInnovation/documents/topten2014/CC-BROCHURE-Top-10-2015](http://innovations.clevelandclinic.org/App_Themes/MedicalInnovation/documents/topten2014/CC-BROCHURE-Top-10-2015)
8. <https://www.centerwatch.com/drug-information/fda-approved-drugs/year/2014>
9. <https://www.centerwatch.com/drug-information/fda-approved-drugs/year/2015>
10. Drug index by: Md Al-amin page 757-763
11. <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm>
12. <http://www.unodc.org/unodc/en/drugs/definitions>
13. <http://www.drugs.com/fda-approval-process.html>
14. [https://en.wikipedia.org/wiki/Surgery#Description\\_of\\_surgical\\_procedure](https://en.wikipedia.org/wiki/Surgery#Description_of_surgical_procedure)
15. [https://en.wikipedia.org/wiki/Organ\\_transplantation](https://en.wikipedia.org/wiki/Organ_transplantation)
16. [https://en.wikipedia.org/wiki/Medication\\_therapy\\_management](https://en.wikipedia.org/wiki/Medication_therapy_management)
17. [https://en.wikipedia.org/wiki/Artificial\\_organ](https://en.wikipedia.org/wiki/Artificial_organ)
18. Hardy, Paul A.; Hardy, Paul A. J. (1997). *Chronic Pain Management: The Essentials*. Cambridge University Press. p. 10. ISBN 978-1-900151-85-6. OCLC 36881282 <http://www.healthline.com/health-news/general-top-innovations-of-2013-120513#2>