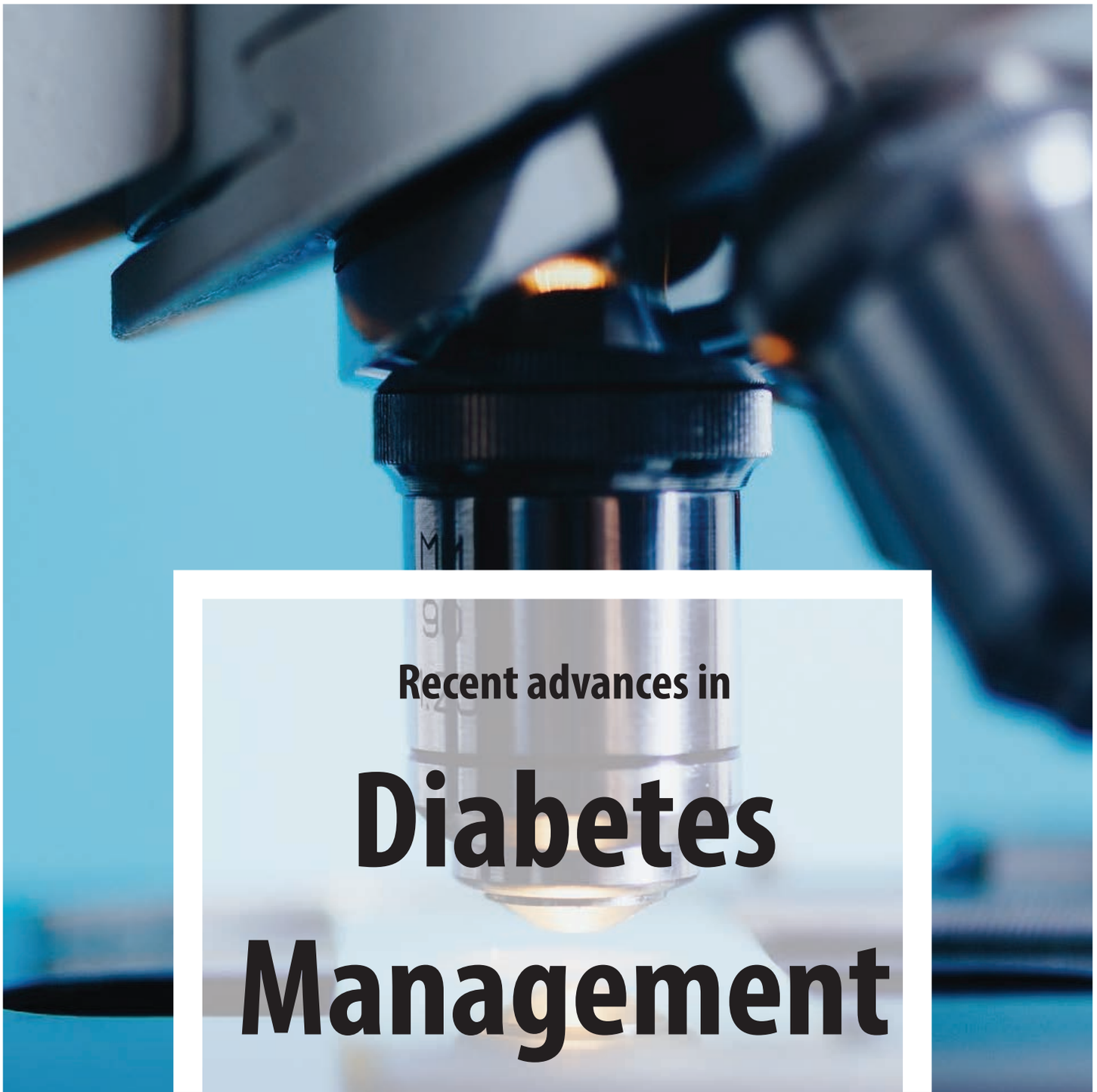

Recent advances in

Diabetes Management

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Clinical studies related to Continuous Glucose Monitoring

The article addresses Medtronic's recent FDA approval of the Guardian™ Connect Continuous Glucose Monitoring (CGM) system. A brief overview of all the clinical studies related to CGM has been presented.

02

Microneedle arrays for insulin delivery

The article analyzes the recent findings on a microneedle system for non-invasive insulin delivery. A birds-eye view of patent filings related to microneedles for insulin delivery, with a focus on global players is presented.

Clinical studies related to Continuous Glucose Monitoring

On March 12, 2018, Medtronic received FDA approval for the Guardian™ Connect continuous glucose monitoring (CGM) system, a smart standalone CGM system for diabetics between the ages of 14 and 75.

The system helps diabetics by intimating them of high or low glucose levels up to an hour in advance. It features a smart diabetes assistant and Guardian™ Sensor 3, the most advanced glucose sensor from Medtronic.

Since its entry into CGMs related research, Medtronic has sponsored over 25 clinical studies related to continuous glucose monitoring, of which 14 studies have been completed. Along with Dexcom and Jaeb Center for Health research, Medtronic forms the top 3 leaders in sponsorship for trials in this domain.

An analysis of the clinical trial studies related to CGM and diabetes since 2000 from clinicaltrials.gov revealed approximately 300 studies including Type 1 and Type 2 diabetes, sponsored by both companies and research institutes. A small subset of these studies also focuses on hyperglycemia and hypoglycemia-related conditions. Apart from these, several clinical studies have been conducted related to glucose levels monitoring for cardiac patients and those with insulin resistance.

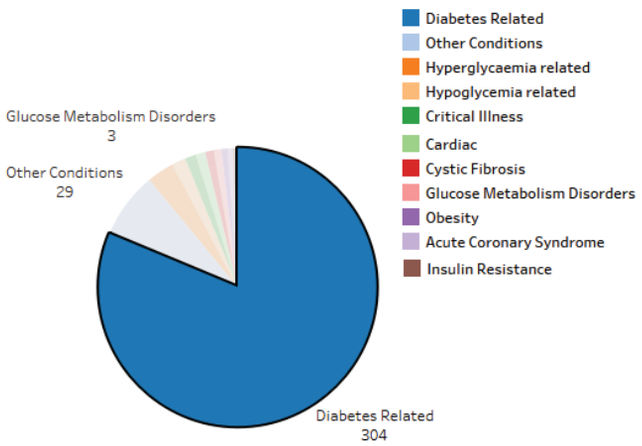


FIG-1a

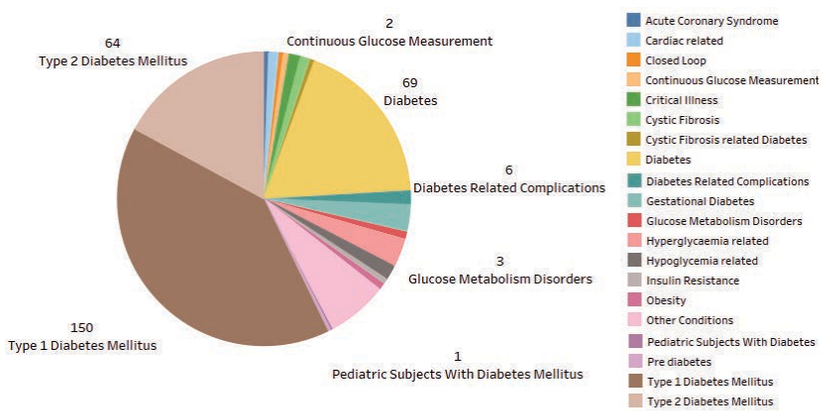


FIG-1b

FIG-1a shows various conditions for which glucose levels have been monitored in clinical trials. These include diabetes related conditions, and conditions related to heart, obesity and cystic fibrosis. Apart from these, glucose level monitoring during pregnancy, paediatric patients with problems related to weight or glucose metabolism, patients with kidney related disorders, conditions related to adenomas and neoplasms, burns and glucose intolerance, patients who have received transplants, patients with immune related conditions, people with injury to the brain or spinal cord, patients with glucose intolerance and stress have been grouped together as 'Other conditions'.

FIG-1b reveals the breakdown for the 304 trials grouped under diabetes related conditions of which 150 are specifically for Type 1 diabetes.

FIG. 2 illustrates the top sponsors of clinical studies related to CGM. 40% of the top sponsors are universities. We note that there are several instances where academic institutes are co-sponsored by one or more industry players such as Medtronic and DexCom.

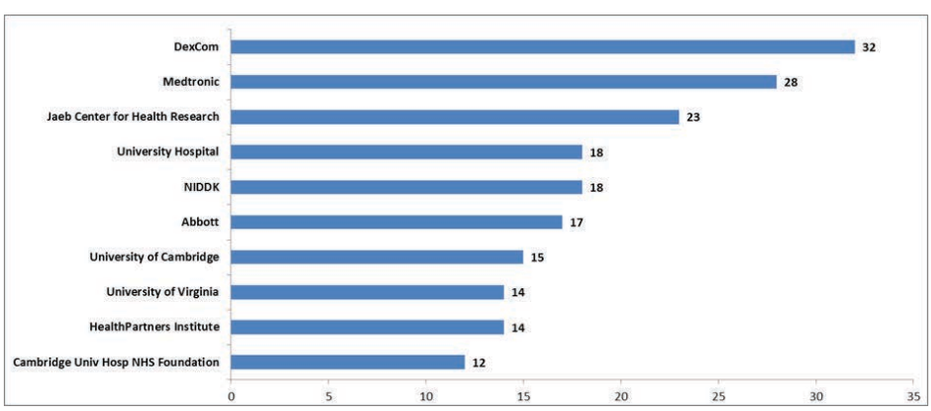


FIG-2

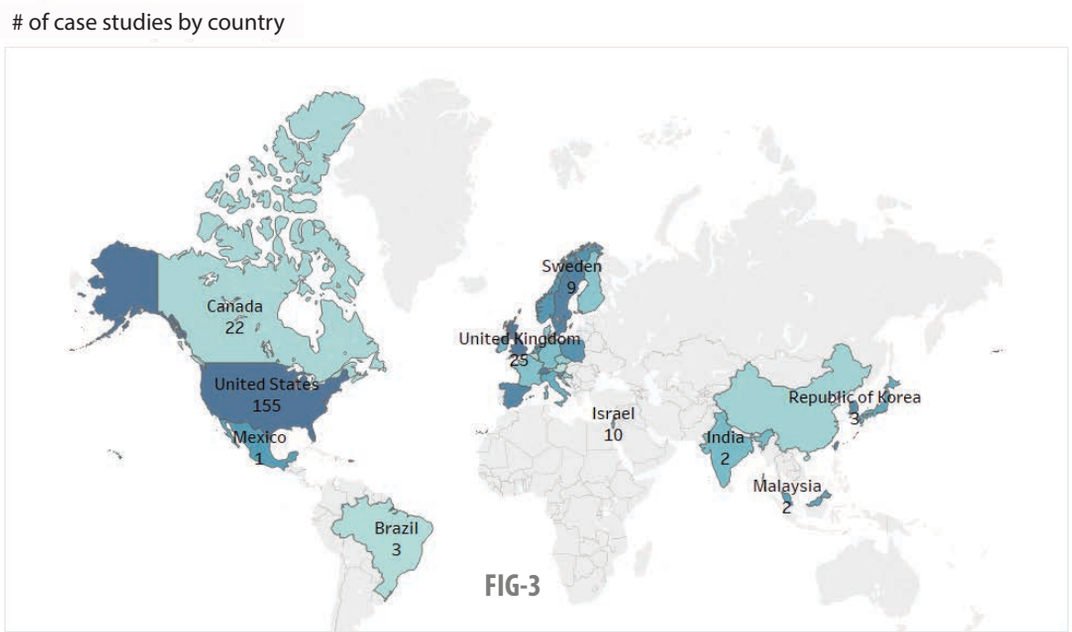


FIG-3

FIG. 3 shows locations where clinical trials related to CGM were conducted revealing that US remains the top choice for a significant number of clinical trials in this particular domain followed by Europe and Canada.

FIG. 4 is a bar chart showing instances where industry is listed as sponsoring a clinical trial relating to CGM reveals equal contribution by industry and other players. Most of the trial cases in CGM domain do not fall into a typical clinical phase I, II, III, IV associated with pharmaceutical drug development as expected for medical devices and systems.

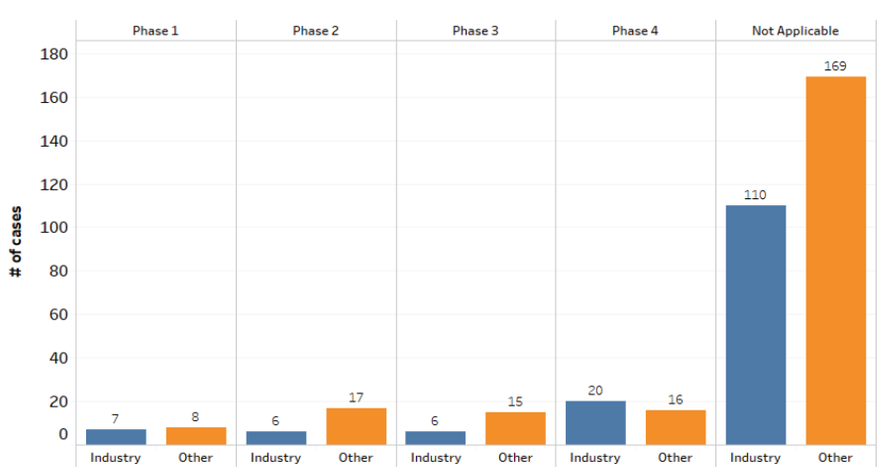


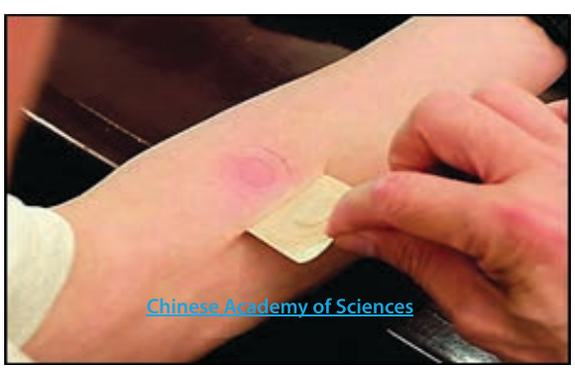
FIG-4

In conclusion, with FDA approval for Guardian™ Connect, Medtronic has taken one step closer to making the lives of people living with diabetes easier. With several clinical trials underway and a few others in the pipeline, we can hope that continuous glucose monitoring will blur the line between diabetics and non-diabetics even further in the coming years.

Microneedle arrays for insulin delivery

Management of glucose for certain conditions involves constant blood monitoring and everyday insulin shots. Scientists are therefore looking at non-invasive methods to avoid pain in people with diabetics. Over the last decade, many different insulin patches have been developed to combat this challenge, but patients still face several issues. In using the dissolvable polymer microneedles patch, for example, the polymer on the needles often deposits on the skin. This stops people from frequent or long-term use of these microneedles. On the other hand, for hydrogel microneedle patches, the efficiency of insulin delivery is poor.

Recent research towards overcoming these issues shows promise in the form of the "smart" patch – a self regulated system to monitor glucose and release insulin in moments of surge in blood glucose. The patch was the result of collaborative research between the University of North Carolina, North Carolina State Univeristy and the Chinese Academy of Sciences, Jilin.



Researchers at the University of North Carolina at Chapel Hill and North Carolina State University developed a microneedle array patch for transcutaneous delivery of nano-sized complex micelles containing insulin and glucose oxidase. The self-regulated system was tested to effectively control blood glucose levels in mouse models. Their results were recently published in a journal article titled, 'Bioresponsive Microneedles with a Sheath Structure for H2O2 and pH Cascade-Triggered Insulin Delivery'. Another group of researchers from Slovenia and Romania have developed a hollow silicon microarray needle for insulin delivery through microinjection. The team of researchers fabricated hollow silicon microneedle arrays to deliver the drug and compare the efficacy against other subcutaneous means of delivery. The hollow microneedle array consisted of 100 microneedles of the following dimensions: 220 µm (height), 130 µm (outer diameter) and 50 µm (inner diameter).

A quick look at the recent patent filings (since 2014) related to microneedle arrays for insulin delivery revealed around 95 patent families.

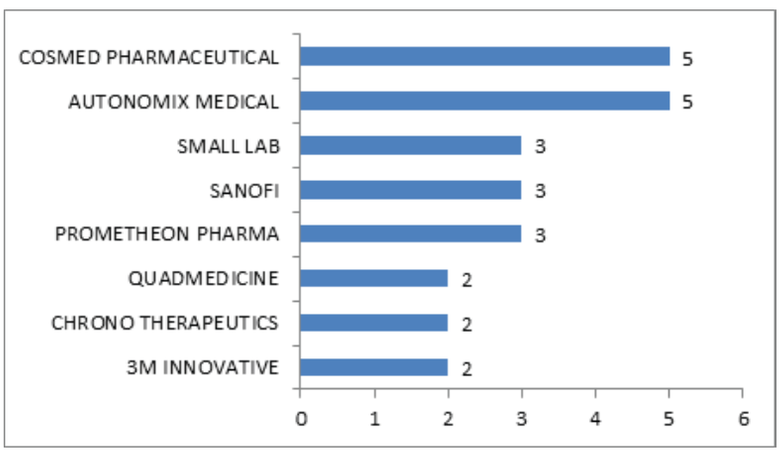


FIG-5

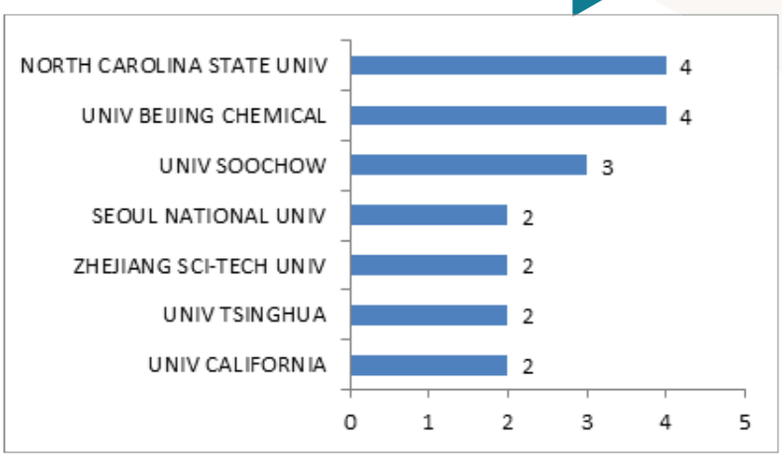


FIG-6

FIG. 5 and FIG. 6 show the top assignees and institutes having patent filings related to microneedle arrays in the last 4 years.

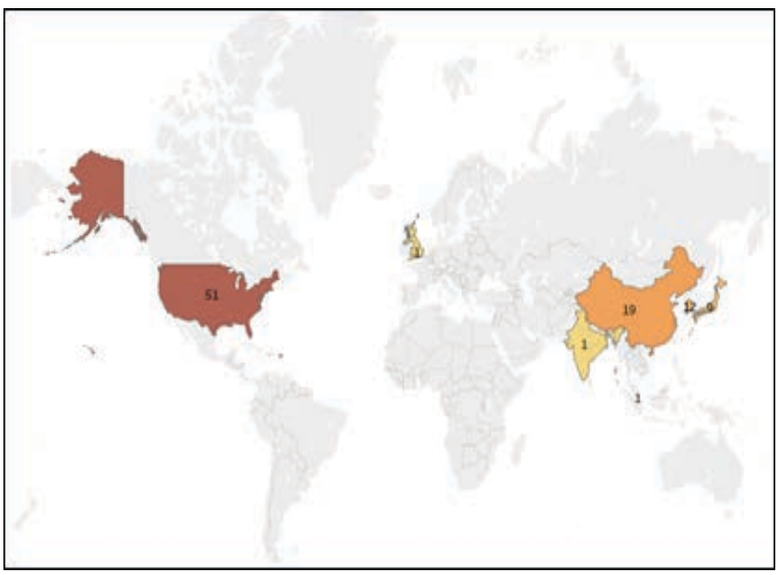


FIG-7

FIG. 7 reveals the priority countries for the 95 patent families showing that US is the largest research base for microneedle array domain in Diabetes followed by Asia (CN, JP and KR).

The "smart" patch has been tested on diabetic mice and they showed to maintain consistent concentrations of insulin in blood. When the mice received a shot of glucose, their blood sugar levels spiked initially, but then fell to normal levels within a couple of hours.

To summarize, microneedle array patches are being designed and tested in animals for efficiency in controlling blood glucose levels. Several groups are working on patches and microneedle arrays for delivering insulin with increased efficiency and bioavailability. As researchers design new array patches with increased advancements and move to human trials we will know how effective these patches are in managing diabetes.

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MaxVal Group, Inc.
2251 Grant Road, Suite B
Los Altos, CA 94024
Phone: 650-472-0644
info@maxval.com | www.maxval.com