

# assessing the **value** of diabetes clinical research

Clinical research is conducted to document the efficacy, safety and optimal use of human medicine. It is a collaborative effort involving many stakeholders, and this study provides insights on the value created in this process.

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# about this study

Clinical trials are a crucial part of the development process for human medicines. Without them we would be unable to document the efficacy, safety and optimal use of the medicines we bring to the people who need them. However, we believe that clinical trials create value in more ways and have set out to investigate four hypotheses about how this could be:



Clinical research leads to improvements in patient care



Clinical research enhances hospital/clinic capabilities



Clinical research helps drive scientific progress



Clinical research has a positive impact on the surrounding economy

This report presents the key findings of a survey we have conducted to test our hypotheses. As a study subject, we found it natural to focus on clinical research within the area of diabetes as this is the field we know most about. As you may or may not know, Novo Nordisk has been researching, developing, manufacturing and selling medicine for treatment of diabetes for more than 90 years. Today, we are widely recognized as the world's leading diabetes care company because of the new innovation we have been bringing to people with diabetes over the years.

This has only been possible due to the thousands of clinical trials we have conducted in a close collaboration with hospitals, patients, healthcare professionals and health authorities all over the world. Our hope is that the study will be a catalyst for discussions about how clinical research can create even more value for all stakeholders involved and society at large.

We would love to hear your opinion.  
Contact us at: [sustainability@novonordisk.com](mailto:sustainability@novonordisk.com)

Note: In this publication, 'industry-sponsored clinical research or trials' and 'clinical research or trials' are synonymous, unless otherwise stated.

TONG YONGXIANG  
Tong has type 1 diabetes  
China

# a responsible approach to clinical research

We are a global healthcare company and the leader in diabetes care. We are increasing our R&D investment and conduct our clinical research using one global standard.



clinical trials to generate data on the efficacy and safety profile of our products, and we promote this data to secure the widest and most appropriate use of our products within the label.

## Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care<sup>1</sup>. Worldwide, 78% of our sales come from our innovative diabetes care portfolio<sup>2</sup>. Our share of the global diabetes market was 27% in 2013<sup>2</sup>.

## Commitment to clinical research

Since 2009, Novo Nordisk has increased R&D spending by an average of around 10.5% per year<sup>2,3</sup>. This stands in contrast to general trends across the industry, where R&D spending has levelled off in recent years<sup>4</sup>. Today, many pharmaceutical companies outsource clinical research to contract research organisations (CROs)<sup>5</sup>, whereas we collaborate directly with the clinical sites using our own organisation when conducting late-phase trials.

In 2012, Novo Nordisk conducted 79 diabetes clinical trials worldwide. In 2014, we had approximately 100 trials ongoing<sup>6</sup>. Looking ahead, the number of people we expect to enroll in diabetes clinical trials between 2014 and 2016 will account for about 69,000 patient years (see glossary, page 30) – compared to 40,000 patient years in the previous three-year span<sup>6</sup>.

## R&D INVESTMENT AND DIABETES TRIALS AT NOVO NORDISK

**2.1** BILLION  
USD

INVESTED IN R&D IN 2013<sup>7</sup>

**~100**

ACTIVE DIABETES TRIALS  
IN 2014<sup>6</sup>



perform clinical trials and clinical activities with the purpose of raising awareness and thereby increasing sales of our products.

## The Novo Nordisk Way

We work in accordance with a set of guiding principles described in the Novo Nordisk Way<sup>7</sup>. The Novo Nordisk Way describes who we are, where we want to go and the values that characterise our company. Three of these values relate to clinical research:

**Our key** contribution is to **discover and develop innovative biological medicines** and make them accessible to patients throughout the world.

**Growing our** business and delivering competitive financial results is what allows us to help patients live better lives, offer an attractive return to our shareholders and **contribute to our communities**.

**Our business** philosophy is one of balancing financial, social and environmental considerations – we call it **'The Triple Bottom Line'**.

## Clinical trial ethics

Novo Nordisk-sponsored clinical trials are performed using one global standard. This standard is developed in accordance with the Declaration of Helsinki and the International Conference on Harmonisation (ICH) Guidelines on Good Clinical Practice (GCP). The Declaration of Helsinki, developed by the World Medical Association, is a standard of ethical principles in clinical trials. The ICH-GCP Guidelines ensure the rights and safety of trial participants and uphold the validity of trial data. For anyone involved in clinical research, the interests of trial participants must take precedence over the interests of science.

## Milestones for insulin treatment in diabetes care<sup>21,22</sup>

1922

### Life-saving diabetes treatment

Isolation of animal insulin (Banting & Best)

1946

### Prolonged action of animal insulin – fewer injections

Animal insulin + protamine (NPH)\*

\*NPH: Neutral Protamine Hagedorn

1980s

### Fewer allergic incidents, scalable production of insulin

Recombinant human insulin

2000s

### Injection immediately before meal – increased quality of life

Rapid-acting modern insulins

### Ease of use, fewer injections

Basal & rapid-acting insulin used in combination

### Less variability, more stable control of blood sugar

Basal modern insulins

2010s

### Lower risk of hypoglycaemic episodes & improved flexibility

New-generation modern insulins/combination insulin

## What will be the next breakthrough?

# what if we stopped innovating?

Diabetes treatment options have improved significantly over the years, but there is still a need for better prevention and treatment.

### Diabetes challenge

Diabetes is a pandemic affecting 387 million people<sup>8</sup> and mostly driven by type 2 diabetes (see glossary). This is about one in every 20 people. It is estimated that around 6% reach a point where they can live a healthy life with diabetes<sup>9,10</sup>.

**387 MILLION**   
PEOPLE LIVE WITH DIABETES TODAY, RISING TO  
**592 MILLION BY 2035<sup>8</sup>**

The goal of diabetes treatment is to keep blood sugar levels at a normal or near-normal level. One key parameter to measure is HbA<sub>1c</sub>, reflecting the average blood sugar level in a patient. High HbA<sub>1c</sub> is associated with increased risk of diabetes complications<sup>11</sup>.

Even small improvements in HbA<sub>1c</sub> can bring significant health benefits. For example, it can be estimated that a 1% drop in HbA<sub>1c</sub> would reduce the number of heart attacks and strokes by 14%, cases of blindness and kidney disease by 37% and diabetes-related deaths by 21%<sup>11</sup> – along with associated reductions in medical expenditures.

Globally, health expenditure due to diabetes in the adult population was estimated at 612 billion US dollars in 2014<sup>8</sup>. Another study showed that 81% of such expenditure in the US is associated with disease complications and productivity losses<sup>12</sup>.

### Need for better diabetes treatment

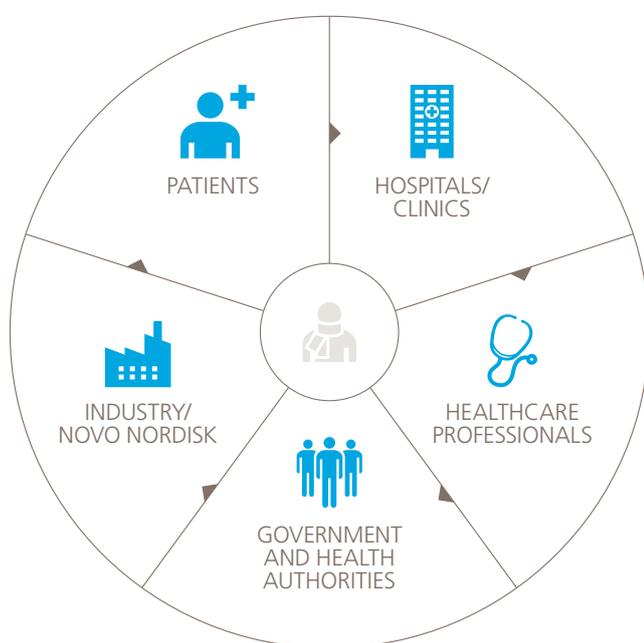
In those countries where mean HbA<sub>1c</sub> levels have been studied in people diagnosed with diabetes, no country reaches a mean HbA<sub>1c</sub> target of < 7%<sup>13-19</sup>.

There have been several studies of the barriers to patients achieving treatment targets. For example the Global Attitudes of Patients and Physicians in Insulin Therapy survey, which was sponsored by Novo Nordisk, found that nine out of ten patients wanted an insulin that maintains blood glucose levels but does not have to be injected every day<sup>20</sup>. In the same survey, seven out of ten physicians said they would treat their patients closer to recommended targets were it not for concerns about hypoglycaemic events (low blood glucose levels), while 67% of patients taking insulin were concerned about experiencing a hypoglycaemic event in the future<sup>20</sup>.

# clinical research enables innovative treatments

To test a new medicine in man is a long journey and requires approvals from regulatory bodies and ethics committees. Along this, the risk-benefit profile of an investigative medicine is frequently and carefully evaluated.

**FIGURE 1 INNOVATIVE TREATMENTS ARE CREATED IN COLLABORATION**



The purpose of clinical research is to evaluate the efficacy and safety profile of a medicine. This is done through a number of trials in accordance with regulatory and ethical requirements.

Clinical trials on new medicine begin only after a drug candidate has first been tested in animals. A protocol describing the trial in details then has to be approved by external health authorities and ethics committees before testing in man can be initiated.

In this case study, we focus only on the activities during clinical research, a process that spans 6 to 8 years on average<sup>6</sup>. It is the most resource-intensive part of R&D in terms of financial commitment and, most of all, patient involvement. It is when a new investigational product is tested in patients through collaboration with a broad range of stakeholders (see Figure 1).

For participating patients and all other stakeholders involved, it is essential to work towards common goals. When stakeholders focus on innovative treatments serving the patients' medical needs, value is created for all.

## clinical research is a collaboration

Clinical research is a complex and highly regulated process. Multiple stakeholders work together in collaboration to achieve beneficial results for all.



### Trial protocol design

- HCPs give scientific and operational input
- Health authority gives input
- Novo Nordisk writes protocol with the primary investigator

Health authority and Ethics Committee approve protocol ✓

## FIGURE 2 RESEARCH & DEVELOPMENT (R&D) PROCESS

The R&D process includes activities through which innovation is transformed into patient care.



### The primary aim of each phase:

**PHASE 1** Starting with very low doses, the safety of the first administration of the drug in humans, usually healthy volunteers, is evaluated in small single- and multiple-dosing trials.

**PHASE 2** Larger trials to investigate dose-response of effect and safety signals, often including comparison with a well-known drug.

**PHASE 3** Further evaluating safety and efficacy in large-scale trials of longer duration to confirm effect and safety profile in a broader population. Often tested in comparison or combination with other drugs. Marketing applications can generally be filed after a successful phase 3 trial.

**PHASE 4** Trials conducted after market authorisation to obtain further safety and efficacy data and further document the risk-benefit profile either in a real-life setting or in accordance with specific requests from the authorities as a condition for approval.



#### Patient recruitment

- HCPs agree to screen patients at hospitals/clinics for inclusion
- Novo Nordisk supports the conduct of the trial

Patients volunteer to participate in a trial and sign informed consent ✓



#### Patients in trial

- HCPs treat and educate patients at hospitals/clinics
- Patients follow the treatment as described in the protocol
- Safety and efficacy data from patients are sent to Novo Nordisk by HCPs
- Novo Nordisk supports and audits
- Authority audit

Patients complete trial and return to normal care ✓



#### Results reporting

- Novo Nordisk analyses data and shares it with the HCPs involved
- HCPs write publications in collaboration with Novo Nordisk
- Public access to data

Safety and efficacy data documented and publicly available ✓

# shared value comes from collaboration

Our greatest contribution to society is meeting unmet medical needs through our products. The better our products, the greater benefit for us and our stakeholders.

At Novo Nordisk, the patient is at the centre of everything we do. We aspire to have a genuine understanding of the needs of our patients, as well as the needs of those with whom we collaborate, such as healthcare professionals (HCPs), government authorities and business partners. This understanding builds mutual trust and creates new opportunities for further growth.

No one can fight the diabetes epidemic alone, and inherent in the concept of shared value is a recognition of the need to work together. The sum of what stakeholders can achieve together far exceeds what any single actor can achieve in isolation.

## The study

The stakeholder value created in the process of clinical research is regularly under-recognised.

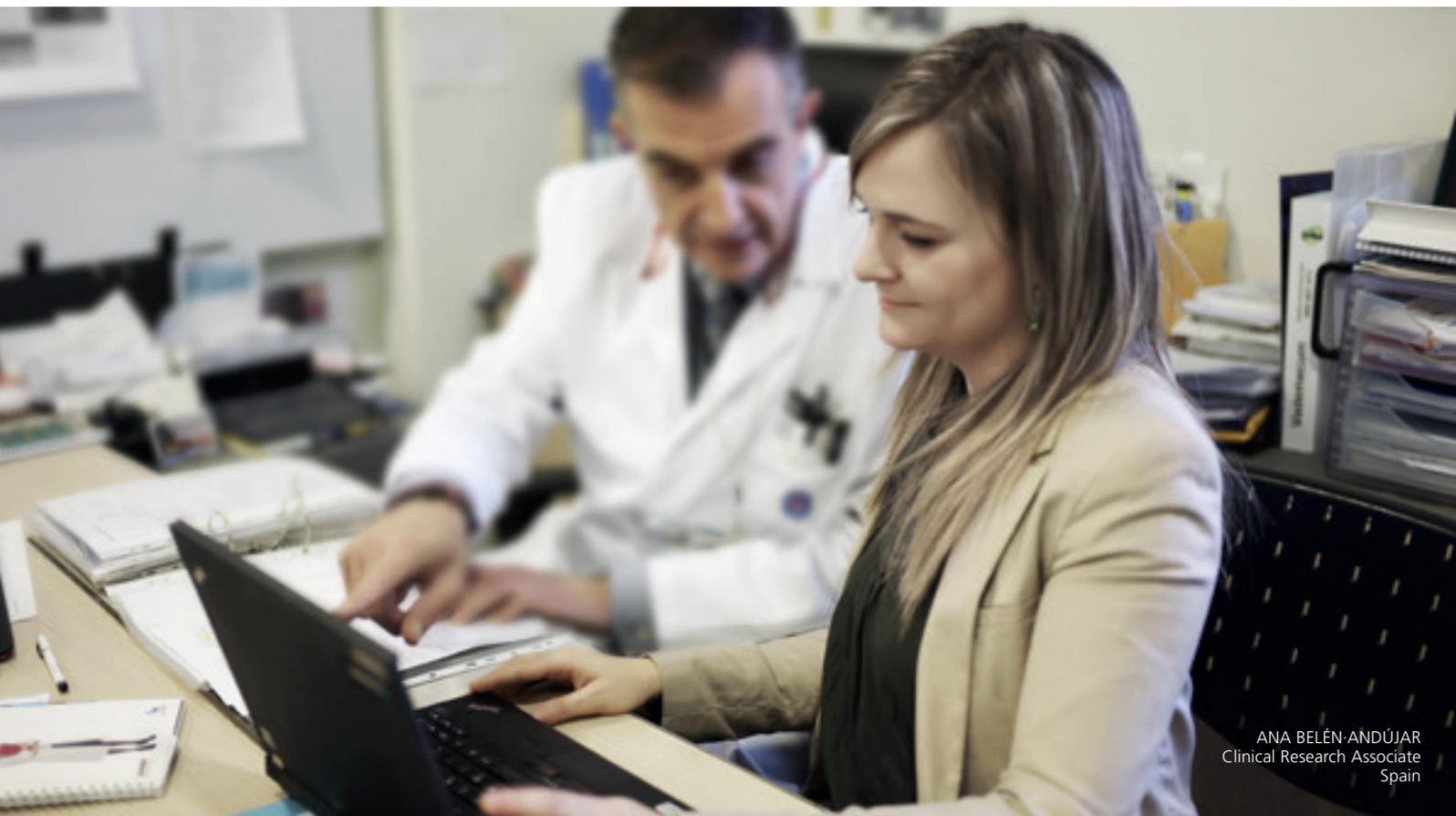
By testing the four hypotheses (see Figure 3), we aim to understand and make any potential value created for the five stakeholder groups (HCPs, patients, government/health authorities, hospitals/clinics and the pharmaceutical industry/ Novo Nordisk) more transparent.

This study is based on extensive qualitative interviews and a quantitative survey of patients and HCPs from Denmark, India and the US who have participated in diabetes clinical trials, including at least one with Novo Nordisk (see methodology, page 28)<sup>23</sup>. All the results and conclusions are representative of the people who have participated in our interviews and survey, and are solely indicative of the general setting of clinical research.

- 89 qualitative interviews with HCPs, patients and other stakeholder representatives
- 347 survey responses from HCPs and patients

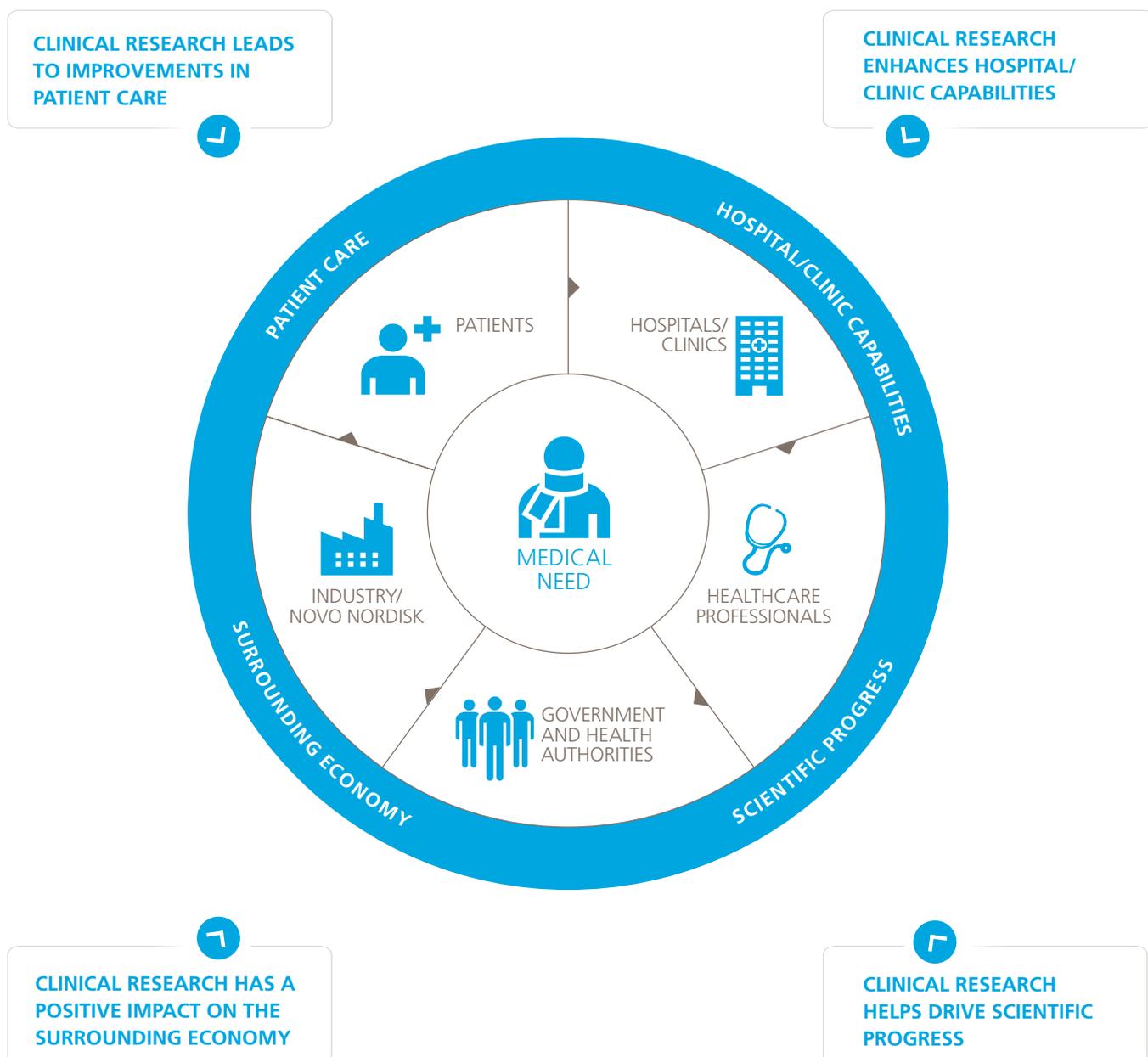
In addition to the qualitative interviews and quantitative survey, several other analyses were performed to test our hypotheses, such as

- a literature review
- a job impact analysis
- an analysis of our own data on file



**FIGURE 3 HYPOTHESES OF SHARED VALUE CREATION IN CLINICAL RESEARCH**

When the five stakeholder groups align their focus on medical needs, value is created for all within four key areas (blue ring).





# creating shared value





# clinical research leads to improvements in patient care

The training that patients receive through participation in clinical research may enhance their self-management capabilities, leading to overall health improvements and benefits extending beyond the duration of the trial.

Clinical research is an important contributor to improved diabetes care. Clinical research enables the development of innovative products and supports patients in reaching the goal of keeping blood sugar levels at a normal or near-normal level<sup>23</sup>.

## Patient-perceived value creation

According to the respondents, health improvement is just one of many benefits of patient participation in clinical research. In our survey, patients were asked to assess the value they personally have derived from participating in clinical research by ranking statements from the most to least important for them. In rank, the top five benefits cited by patients were<sup>23</sup>:

- 01 Overall health improvements**
- 02 Benefits from the increased expertise and knowledge of HCPs involved in clinical trials**
- 03 Improved blood sugar control**
- 04 Increased knowledge of how to manage diabetes**
- 05 Clinical research facilitates new products to market which increases options for patients**

## Intensified care in the clinical trial setting

Patients participating in clinical research may receive more personalised and intense care during the study than outside the study. In some recent global Novo Nordisk clinical trials, for instance, patients have visited HCPs four times more often and received twice the number of tests and other diabetes-related measurements than recommended in the national Danish guidelines for diabetes care<sup>25,6</sup>.

There is research indicating that closer titration surveillance<sup>26-29</sup> and frequent medical visits<sup>30</sup> lead to improved health and may foster a stronger HCP–patient relationship, creating opportunities for patients to learn self-management techniques.

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**80% OF  PATIENTS**

SAID THAT THEIR INVOLVEMENT IN A CLINICAL TRIAL IMPROVED THEIR HbA<sub>1c</sub> LEVELS<sup>23</sup>

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## Positive impact on health outcomes

The quantitative survey shows that 90% of patients rate their overall clinical trial experience as positive<sup>23</sup>. In addition, health improvements resulting from clinical trials are evident to patients and HCPs. In addition to the highlighted statistic on page 12, 86% of HCPs believe that HbA<sub>1c</sub> levels have improved in their patients who have participated in a clinical trial, while 88% believe that patients' overall health has improved as a result of clinical trial participation<sup>23</sup>.

**“[Clinical research] has given me the confidence that I can live with diabetes under control.”**

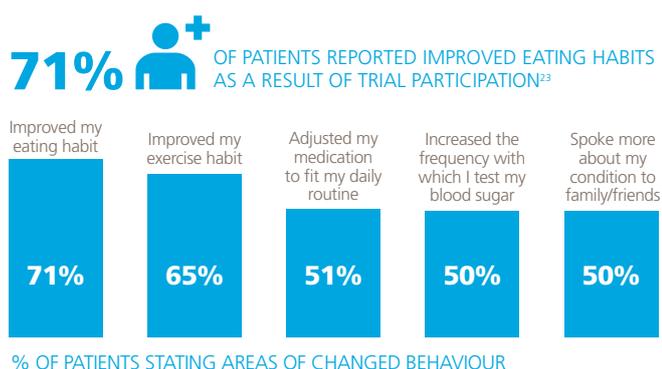
PATIENT, INDIA

Lowering the HbA<sub>1c</sub> level is associated with lower risk of complications due to diabetes<sup>11</sup>, and thus is generally linked to increased quality of life for people living with diabetes.

## Long-term benefits for patients

For patients with chronic illnesses such as type 2 diabetes, long-term lifestyle changes are important. A patient who might live with a condition for the rest of his or her life must learn how to manage it. In that sense, the knowledge and skills that patients gain from their participation in clinical research have lasting value, as shown in Figure 4. Many patients with diabetes would like to understand more about their condition, how to manage it and how to stay healthy<sup>31</sup>. Participation in

**FIGURE 4 CHANGES IN HEALTH HABITS**



clinical research increases patients' knowledge, and 85% of patients in our survey say that participating in clinical research improved their understanding of diabetes<sup>23</sup>.

In our survey, 74% of HCPs agreed that the benefits of participation for patients extend beyond the duration of the clinical trial<sup>23</sup>.

In our survey, most patients said that trial participation motivated them to change their diet and lifestyle behaviours (Figure 4)<sup>23</sup>. Moreover, 87% of patients had set health-improvement targets for themselves and 60% had changed their diet and lifestyle goals<sup>23</sup>, offering the potential for sustained, long-term health improvement.

## AREAS OF CONCERN

The study also indicated some areas where patients and HCPs felt that improvements could be made.

**29%**

OF HCPs FEEL WELL TRAINED ON TRANSITIONING PATIENTS BACK TO NORMAL CARE<sup>23</sup>

## Transition to normal care

Our survey revealed that there may be value in looking into the process of transitioning patients in clinical trials back to normal care, as too few HCPs feel well trained to do that.

**26%**

OF PATIENTS SAID THAT DIFFICULTY ACCESSING DATA IS A NEGATIVE ASPECT OF CLINICAL TRIALS<sup>23</sup>

## Communication about trial results

Data also suggests that there is room for improving industry communication with patients. More than a quarter of patients said that one of the negative aspects associated with clinical trials is difficulty accessing clinical research data. Patients expressed a preference for having all collected outcomes data reported back to them<sup>23</sup>. Of those patients to whom trial results were reported, 92% found the information to be valuable<sup>23</sup>.

# clinical research enhances hospital/clinic capabilities

The skills that HCPs gain from participation in clinical research can ultimately lead to improvements in patient care and research conduct at the hospital or clinic.

Medical research is not part of the educational curriculum for medical students in many parts of the world. Clinical research can fill the gap, creating value by strengthening research capabilities in the hospital and improving HCPs' patient care competencies in the clinic.

## HCP-perceived value creation

In our survey, HCPs were asked to assess the value they personally have derived from participating in clinical research by ranking statements from the most to least important for them. In order, HCPs cited these top five benefits of participation in clinical research<sup>23</sup>:

- 01** Provides increased understanding of the clinical trial process to better interpret clinical data
- 02** Improves the monitoring and management of patients with diabetes
- 03** Facilitates use of new treatments
- 04** Increases familiarity with a treatment prior to potential approval
- 05** Allows making better/more informed treatment choices for patients

## Enhanced hospital research capabilities

Clinical research brings with it a discussion about research methods and data interpretation within an institution. This discussion helps HCPs to better evaluate treatments and apply the knowledge that they gain to patient care or other research activities, such as independent or academic research<sup>23</sup>. Our survey also revealed that 76% of HCPs believe that industry-sponsored trials contribute to improvements in clinical research conduct<sup>23</sup>.

For research institutions, clinical research experience brings with it additional benefits in terms of improvements in the quality and day-to-day running of trials, documentation processes, the design of protocols and the communication of trial data to trial participants, to name just a few<sup>23</sup>.

Our survey found that over half of HCPs who have participated in clinical research shared their learnings with professional colleagues, thereby helping to spread best practices<sup>23</sup>. Furthermore, more than a third of HCPs believed there was a knock-on effect on other doctors at the clinic who did not participate in the trial<sup>23</sup>.

Clinical research may also free up time and resources for other purposes, such as patient care, HCP and staff training, and conduct of the independent research at the hospital or clinic<sup>23</sup>.

We also partner widely with clinical research sites, contributing to the competencies built at those sites. In India, for example, half of the participating sites gained new insight into a new therapeutic class<sup>\*32</sup>.

**76%**  **OF HCPs**

SAY THAT INDUSTRY-SPONSORED TRIALS HAVE CONTRIBUTED TO IMPROVEMENTS IN CLINICAL RESEARCH CONDUCT AT THEIR INSTITUTION<sup>23</sup>

## Improved patient care in the clinic

In mature healthcare systems, HCPs are routinely trained to care for people with diabetes. But in many other places, including developing nations where the diabetes population is growing quickly, HCPs may receive little or no formal instruction in diabetes care<sup>33,34</sup> – highlighting the urgent global need to train HCPs in diabetes care.

**“Clinical research helps us establish what is considered a safe practice. It helps us design protocols for care.”**

NURSE ASSOCIATION STAKEHOLDER, USA

Around half of HCPs who responded to the recent Diabetes Attitudes Wishes and Needs (DAWN™) study sponsored by Novo Nordisk said they want more training in diabetes patient self-management, motivation and nutrition<sup>31</sup>. Although clinical trial experience cannot replace formal instruction, it provides HCPs with tools they can use to improve patient care. Clinical

\*A new class of injectable drug for the treatment of type 2 diabetes (GLP-1).



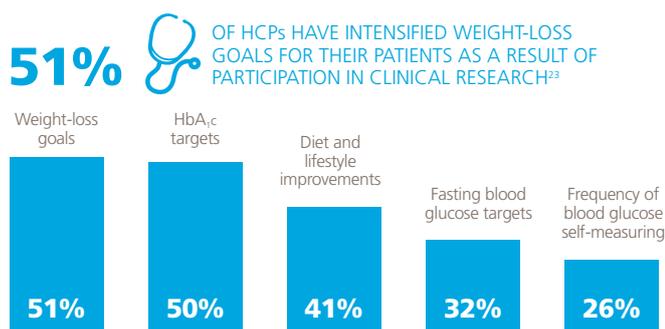
research activities may have a downstream impact on patient care in general and on the care of people with diabetes in particular. Our survey revealed that many HCPs believe that their participation in clinical research improves both care

**75%**  **OF HCPs**

**BELIEVE THAT CLINICAL TRIALS CONTRIBUTE TO OVERALL IMPROVEMENTS IN TREATMENT AND PATIENT CARE AT THEIR HOSPITAL/CLINIC<sup>23</sup>**

practices within their institutions and glucose control within their own patient populations<sup>23</sup>. 69% of HCPs have intensified treatment targets or goal setting with all their patients as a result of participation in clinical research<sup>23</sup>. These goals and

**FIGURE 5 HCPs INTENSIFY CARE TARGETS**



% OF HCPs SAYING THAT THEY HAVE INTENSIFIED THE GIVEN TARGETS OR GOALS AS A CONSEQUENCE OF PARTICIPATION IN CLINICAL RESEARCH

**33%**  
**OF SPECIALISTS FEEL WELL INFORMED ABOUT COMMUNICATING POTENTIAL BENEFITS AND RISKS OF THE TRIAL TO PATIENTS<sup>23</sup>**

targets, depicted in Figure 5, include weight-loss goals, HbA<sub>1c</sub> targets and diet and lifestyle improvements – all of which create a foundation for patient awareness of diabetes and prevention of disease progression.

### AREAS OF CONCERN

Our survey revealed an opportunity for the industry in general to improve communication with HCPs about various aspects of clinical research.

### Communicating risks and benefits about participation in a trial

During trials, there is a procedure through which all HCPs are trained in communicating the benefits and risks of trial participation to the patients. Despite this, in our survey only 33% of specialists said that they felt they knew enough to communicate risks and benefits of the trial to patients<sup>23</sup>.

71% of HCPs rated access to trial outcomes as ‘quite good’ or ‘very good’<sup>23</sup>. For all trials, there is a system for accessing data, but there may be additional value in looking at how data is shared with HCPs and how HCPs can most easily share data with patients. This is evidenced by the fact that 93% of HCPs who had trial results shared with them, found them to be valuable<sup>23</sup>.

# clinical research helps to drive scientific progress

The scientific advancements deriving from clinical research are spread through networks and scientific journals, encouraging best practices in patient care.

Few people with diabetes reach desired treatment outcomes<sup>9,10</sup>, so there is a clear need for innovation in diabetes care. Scientific knowledge generated through clinical research drives innovation that addresses unmet treatment needs.

## Drivers of collaboration

HCPs are interested in advancing clinical research when it is meaningful, ethical and makes a difference to patients. The treatment under investigation is important to 94% of HCPs when considering whether to participate in clinical research<sup>23</sup>, as shown in Figure 6.

Over the years, Novo Nordisk's clinical research has yielded scientific advancements that have driven new treatments to market. This research would not be possible without HCP involvement.

**FIGURE 6 FACTORS GOVERNING HCP TRIAL PARTICIPATION**



% OF HCPs WHO SAID THAT THE GIVEN FACTORS WERE IMPORTANT IN THEIR DECISION TO PARTICIPATE IN A PARTICULAR TRIAL

Working with the pharmaceutical industry provides HCPs with additional insights. In fact, 91% of HCPs say they gain scientific knowledge from working directly with pharmaceutical companies<sup>23</sup>.

## Scientific networking

When participating in clinical research, HCPs gain access to scientific networking opportunities<sup>23</sup>. These networking opportunities – scientific meetings, talks and other peer

activities – allow HCPs to learn from their colleagues and share information. Scientific networking also enhances their professional reputation in their fields.

**91%**  **OF HCPs**

SAY THAT PARTICIPATION IN CLINICAL TRIALS GIVES THEM ACCESS TO NEW SCIENTIFIC NETWORKS<sup>23</sup>

## Knowledge dissemination through publications

The value of new scientific knowledge is amplified when its reach is broadened. This is accomplished through scientific publications.

HCPs who participate in clinical research often publish their findings in peer-reviewed scientific journals<sup>6</sup>. Publication in a respected journal is a must, as it allows the sharing of knowledge and scientific progress.

**“The knowledge factor is always there. The benefit lasts for a lifetime.”**

ENDOCRINOLOGIST, INDIA

In 2012, Novo Nordisk-sponsored diabetes research resulted in the publication of 159 articles in scientific journals. This continued an upward trend in publications going back a half decade and is three times the number of scientific publications coming from the company ranked as number two<sup>6</sup>.

In itself, the number of publications is of limited importance – quality is an important parameter and can be measured through journal impact factor. The average journal impact factor for all published articles on Novo Nordisk-sponsored research is high – 4.69 out of 5, which is comparable to other industry peers<sup>6</sup>.



## AREAS OF CONCERN

The Novo Nordisk Way describes how we want to work. One essential principle is that “we never compromise on quality and business ethics”<sup>7</sup>. HCPs share our sentiment, feeling strongly that it is important to work with industry partners who also have high ethical standards. Our own survey backs this up: 93% of HCPs consider the ethical standards of the company to be important when deciding whether to participate in a clinical trial<sup>23</sup>.

**28%**

OF HCPs ARE CONCERNED ABOUT BEING PERCEIVED AS HAVING A CONFLICT OF INTEREST AS A RESULT OF PARTICIPATION IN CLINICAL RESEARCH<sup>23</sup>

Despite this, over a quarter of HCPs have concerns about being perceived as having a conflict of interest if they participate in clinical research.

**“It is a concern that we risk being biased towards the companies we work with. It is up to the individual doctor to remain objective.”**

ENDOCRINOLOGIST, DENMARK

# clinical research has a positive impact on the surrounding economy

Clinical research may result in job creation in the surrounding economy as well as earlier diagnosis of complications of disease during the trial.

The economic impact of clinical research may be measured in many ways: job creation and the downstream effects of putting people to work, to name just a few. In addition, clinical research may drive long-term value for society through cost reductions associated with health improvements.

The pharmaceutical and biotech industries reinvest far more sales revenue – 15.1% – back into research and development than any other industry<sup>24</sup>.

## Economic and health benefits in developing nations

The diabetes population is growing fast, particularly in low- and middle-income countries, and the growth rates in developing nations are outstripping those of the US and many European nations<sup>3</sup>. The fact that 77% of people with diabetes live in low- and middle-income countries dispels the notion that diabetes is a disease of the wealthy<sup>8</sup>.

In reality, those at the lower end of the socioeconomic scale are most vulnerable. A research presence in developing nations may be critical for extending outreach to these populations.

The share of clinical trials we have conducted in developing nations has more than doubled in the last five years.



NOVO NORDISK'S CLINICAL TRIALS IN 2013 WERE CONDUCTED IN DEVELOPING COUNTRIES, COMPARED TO 15% IN 2009<sup>6</sup>

## Job creation

One of the most tangible benefits of clinical research is job creation. Job creation extends beyond simply the number of direct hires in clinical research; it also includes jobs created through employee and supplier responding. In Denmark, according to our internal calculations, it is estimated that each clinical research hire at Novo Nordisk results in the creation of three jobs<sup>6</sup>. This is also supported by the 2013 EFPIA report, which states that "the research-based pharmaceutical industry generates three to four times more employment indirectly than it does directly"<sup>24</sup>. In the US, the ratio is one to five. In India,

where the cost of living is lower, the 'multiplier effect' (see page 29) is even more pronounced: nine jobs are created for each clinical research employee hired<sup>6</sup>.

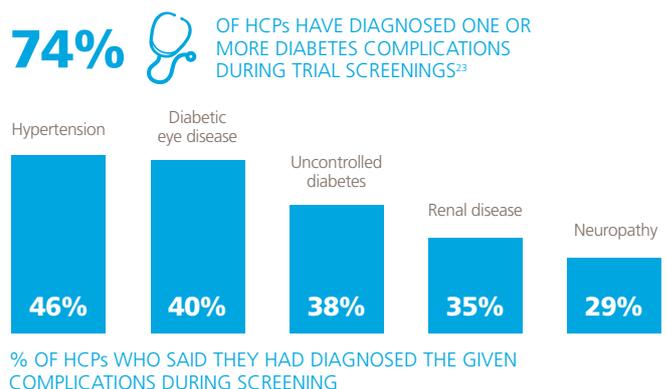


As a result of clinical research activities in the US, Denmark and India alone, we were responsible for the creation of more than 2,700 jobs in 2013<sup>6</sup> (see methodology, page 29). This is a small but important part of the socioeconomic improvements in the nations involved.

**"For every dollar spent on medical research you have another four spent on all the other stuff – job creation and so forth. So, there are lots of ancillary benefits to society as well."**

PATIENT ASSOCIATION STAKEHOLDER, USA

**FIGURE 7 EARLY DETECTION OF COMPLICATIONS**



### Detecting complications early

The benefits of clinical research are also measured in terms of health economics. Patients' participation in clinical trials leads to a reduction in blood glucose levels<sup>23</sup>, which is associated with a reduced risk of costly complications<sup>11</sup>.

A US study estimates that more than half of the cost of diabetes is associated with diabetes-related complications, such as heart attacks, limb amputations, blindness and kidney disease<sup>12</sup>.

When patients enter clinical research, they are screened thoroughly for health status and eligibility for a clinical trial. Often during the screening process, potential complications of diabetes are discovered in people who may believe they are healthy – 74% of HCPs said they had diagnosed one or more diabetes complications during trial screenings<sup>23</sup> (Figure 7). In these cases, screenings may provide a better chance of heading off costly complications and saving lives.



# the **value** for Novo Nordisk

Our long-term engagement with HCPs and focus on a high level of scientific and process quality facilitates an engaging environment that supports Novo Nordisk's commitment to bring new safe and effective medicines to patients faster.

## Data on the safety profile and efficacy of a new medicine is key

A key outcome of clinical research for Novo Nordisk is the generation of safety and efficacy data. This data is necessary for providing the authorities with sufficient documentation to obtain approval for the launch of a new product or to extend the labelled use of an existing product.

## Stakeholder engagement creates value

Novo Nordisk focuses on stakeholder engagement that helps us to build relationships and trust with patients and HCPs. Working with HCPs in a transparent and respectful manner is important. HCPs who participate in clinical research gain new skills, knowledge of disease and treatment, and access to a new professional community. This helps create a positive reputation for clinical research and benefits Novo Nordisk by increasing access to world-class scientists and facilities.

An appreciation of this approach may be seen in a shift in HCP attitudes towards clinical research from before to after trial participation. Before trial participation, 24% of HCPs had a

negative or neutral preconception of trial conduct, compared to just 2% after trial participation<sup>23</sup>.

**90% OF**  **PATIENTS**  
REPORTED THEIR OVERALL TRIAL PARTICIPATION  
EXPERIENCE AS POSITIVE<sup>23</sup>

Research facilities that have frequently collaborated with Novo Nordisk on clinical trials choose to work with us again. Of the US clinical research sites currently working with us, 65% have partnered with us in the past<sup>6</sup>. This may indicate that our focus on stakeholder engagement helps us to build long-term relationships with research sites to the benefit of Novo Nordisk, HCPs and patients.

## High scientific and process quality creates value

Attention to scientific and process quality also yields specific benefits for Novo Nordisk.



The ability to discuss medical needs with the HCPs close to the patients enables Novo Nordisk to design the clinical trials to better evaluate the profile of new medicines and ensure it serves real patient needs.

Our focus on scientific quality and stakeholder engagement allows us to initiate clinical trials quickly. Novo Nordisk is among the fastest in the industry at enrolling patients for clinical research<sup>35</sup>. Efficient clinical trials shorten the timeline for submission of a new medicine for regulatory approval. Faster approval results in faster access to new medicines for people living with diabetes and for HCPs who are committed to getting their patients the best possible care. Faster approval also leads to a faster return on investment for Novo Nordisk.

Furthermore, we have high screening success rates<sup>36</sup>. When patients are screened for participation in clinical research, they must exhibit a specific clinical and demographic profile, such as disease severity, symptoms, age, gender (inclusion and exclusion criteria), to ensure that they are the right candidates to participate in the research being conducted. This is important from an ethical standpoint, for the quality of the

trial outcomes and to ensure that a new medicine is studied in patients who might benefit from it.

When patients fail to meet the screening criteria, more patients need to be screened. Hence, screening failures are costly for Novo Nordisk and may also be a negative experience for patients. In the period 2008–2012, Novo Nordisk's screening success rate was 35% higher than the industry average in diabetes phase 2 and 3 trials.

**35% HIGHER**

SCREENING SUCCESS IN NOVO NORDISK'S CLINICAL TRIALS  
THAN THE INDUSTRY AVERAGE\*<sup>36</sup>

The US Food and Drug Administration recommends examination of the screening failures as part of a performance indicator during monitoring of a clinical trial to enhance human subject protection and the quality of clinical trial data<sup>37</sup>. This highlights the importance of carefully designed inclusion and exclusion criteria, which are not unnecessarily restrictive<sup>38</sup>.

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# the **novo nordisk way** of conducting clinical research

We put the patients at the centre of everything we do, and we critically evaluate every part of our business to see how we can create greater value for all our stakeholders.

The Novo Nordisk Way of conducting clinical research is based on global standards and executed with an overarching focus on engaging with our stakeholders and maintaining a high level of scientific and process quality (Figure 8).

## STAKEHOLDER ENGAGEMENT

Novo Nordisk is transparent in its study processes, rationale and outcomes. We pursue ongoing, open communication with stakeholders, rooted in a sense of accountability and guided by a desire for mutual respect. This creates trust with patients and trial investigators.

## SCIENTIFIC AND PROCESS QUALITY

Keeping the patient at the centre of clinical research and striving for the best scientific results require attention to rigorous science and processes. In our clinical research activities, we focus on the quality of scientific endpoints and the simplicity of processes. Our clinical research staff have strong scientific and operational expertise.

**FIGURE 8 THE NOVO NORDISK WAY OF CONDUCTING CLINICAL RESEARCH**



The key contribution of Novo Nordisk is to discover and develop innovative biological medicines and make them accessible to patients throughout the world.

In conducting clinical research, Novo Nordisk does it in the following way:



### **WE SUPPORT THE DEVELOPMENT OF RESEARCH SITES**

We work with our partners to develop necessary capabilities, for example staff training and research competencies, which helps ensure high-quality data for our trials and potentially future trials with other sponsors. This benefits Novo Nordisk and in addition patients and HCPs long after the trial ends.



### **WE CREATE RELATIONSHIPS WHEN EXECUTING CLINICAL TRIALS**

Novo Nordisk does not outsource late-phase clinical trials to CROs. We prefer to generate the scientific advancements in direct collaboration with our investigators.



### **WE ADVANCE TREATMENT AREA EXPERTISE**

As a result of clinical research, learnings from a trial about the treatment area, the conducting of the trial and the techniques used are analysed and shared through meetings with the participating HCPs, thus contributing to the spread of scientific knowledge and learning.



# summary

Our assessment shows that value is created in the process of diabetes clinical research beyond efficacy and safety-data generation.

## BACKGROUND AND OBJECTIVES

Clinical research is an essential part of product development and is conducted in collaboration with multiple stakeholders who work together in accordance with regulated procedures. The value created for these stakeholders in the process of clinical research is often under-recognised.

We have therefore investigated the shared value created by clinical research based on the four hypotheses that clinical research leads to improvements in patient care, enhances capabilities at the participating hospital/clinic, helps drive scientific progress and has a positive impact on the surrounding economy.

## OUR ASSESSMENT

Qualitative interviews and quantitative survey to investigate the shared value of clinical research were performed with participants from Denmark, India and the US. The 89 qualitative interviews with healthcare professionals, patients and other stakeholder representatives were used to shape the double-blinded quantitative survey, which had 347 healthcare professionals and patient respondents.

This is an initial attempt at qualifying our hypotheses. A study of this size and scope have some limitations but we think the conclusions can be supported and that it qualifies a debate about the shared value created through clinical research.





RUILING YANG  
Ruiling Yang has type 2 diabetes  
China

## CONCLUSIONS

The initial hypotheses can be supported by conclusions from the qualitative interviews, the quantitative survey and internal data analyses as described below:



### Improvements in patient care

Patients participating in clinical research may enhance their self-management capabilities, leading to overall health improvements and benefits potentially extending beyond the duration of the trial.



### Enhanced capabilities at the hospital/clinic

Healthcare professionals learn new skills through clinical research. These improved skills can ultimately lead to improvements in patient care and research conduct at the hospital or clinic.



### Scientific progress

The scientific advancements resulting from clinical research are spread through networks and scientific journals, encouraging best practice in patient care.



### Positive impact on the surrounding economy

Clinical research results in job creation in the surrounding economy and in early diagnosis of diabetes complications for patients screened in a trial.



## reflections

Based on the results of the study, we have reflected on the opportunities to enhance the additional value created by clinical research and areas where we may improve.



From the analysis, it appears that patient care could be improved through a better transition of patients from participation in clinical trials to normal care. In this way, some of the good health outcomes from the trial may be sustained. In addition, self-management may be enhanced with improved communication about health outcomes to patients.



Another opportunity is to improve the hospital/clinic capabilities. These may be enhanced by giving healthcare professionals the tools to share the trial results and learnings they get from the process of participation in clinical research. This is relevant both locally at the hospitals/clinics and at conferences and training events.



Understanding the stakeholder value created by the process of clinical research is relevant for Novo Nordisk. It appears that our long-term engagement with stakeholders and focus on a high level of scientific and process quality facilitate an engaging environment that enables us to bring new safe and effective medicines to patients across the world.

A next step for us could be to carry out a more in-depth analysis of some of the findings in consultation with stakeholders, define courses of action and improve how we create value for the stakeholders involved in the process of clinical research.

# methodology

The data presented in this case study have been produced using a combination of methods leveraging primary and secondary research.

This report is a part of the Blueprint for Change Programme’s series of case studies.

## The Blueprint for Change Programme

The Blueprint for Change Programme increases understanding of how our company creates shared value through our Triple Bottom Line business principle. Through case studies, the programme identifies drivers of value creation and showcases sustainable business approaches. The learnings from these analyses provide Novo Nordisk with opportunities to optimise its approach to working with stakeholders.

## Value appraisal

We assess value creation to make the business case for the Triple Bottom Line principle (Figure 9). We create shared value by maximising the upside and minimising the downside for both Novo Nordisk and society.

Maximising the upside means promoting initiatives that have tangible and intangible value. In the context of clinical research, the path to maximising the upside involves improving patient care processes in the short term and sustaining health outcome gains in the long term.

Minimising the downside means encouraging activities that reduce costs and mitigate risks. In clinical research, the path to

minimising the downside could include reducing the number of screening failures in the trial process and reducing the risk of stakeholder miscommunication and mistrust in the long term.

Initiatives that create value for both society and Novo Nordisk are perceived to create shared value.

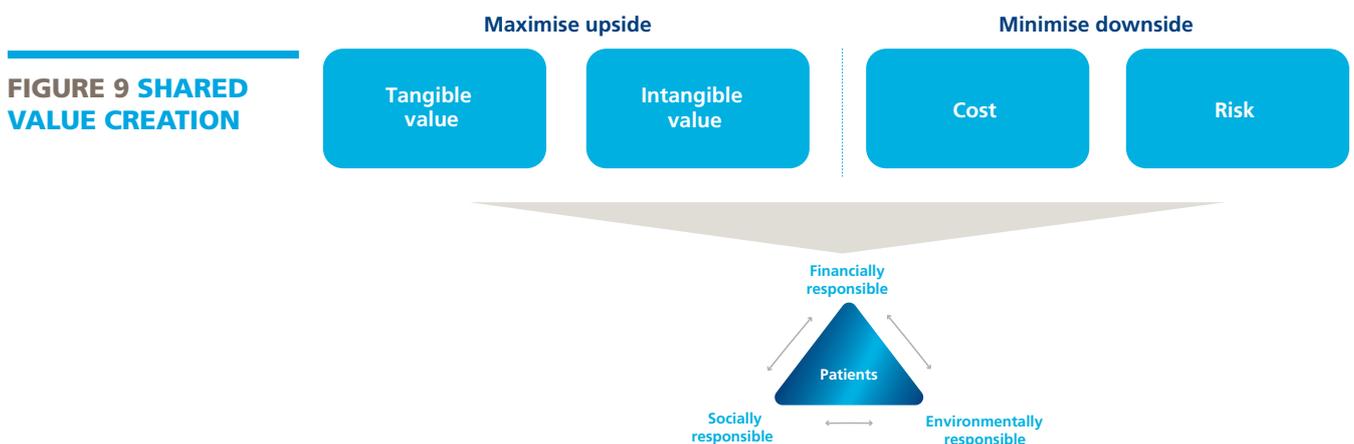
## Qualitative interviews<sup>23</sup>

The qualitative phase involved 89 stakeholder interviews. The purpose of the qualitative interviews was to test our hypotheses in terms of shared value creation in clinical research. Furthermore, the findings of these interviews were tested in workshops and the outcomes used to design the quantitative survey.

Novo Nordisk conducted 13 open, semi-structured, in-person interviews with HCPs who have participated in Novo Nordisk-sponsored clinical research in the US, Denmark and India. A third-party survey provider conducted 68 double-blinded, structured exploratory telephone interviews with patients and HCPs in all three countries on behalf of Novo Nordisk.

Key selection criteria were participation in at least one diabetes clinical trial in the past three years and participation in at least one Novo Nordisk clinical trial.

The same third-party survey provider conducted seven double-blinded, structured telephone interviews with heads of HCP and patient associations and with government officials and payers in the US and one interview with a HCP association from India.



## HCP and patient survey<sup>23</sup>

After the findings on clinical research value creation and potential areas of concern were translated into quantitative studies, the recruitment of diabetes specialists, nurses and patients for a 30-minute online survey commenced.

HCPs included diabetes specialists and nurses from five panels. HCPs were eligible if they had participated in more than two diabetes clinical trials, including at least one Novo Nordisk trial.

Ultimately, 301 HCPs met the selection criteria and 216 (72%) responded to the survey.

The potential pool of patients included patients from eight panels. To be eligible, patients were required to have participated in a minimum of two diabetes clinical trials, at least one of which being a Novo Nordisk trial: 218 patients met the selection criteria, of whom 131 (60%) responded.

Data presented from the survey are generalised to the industry (ie Novo Nordisk and its competitors) and are not Novo Nordisk-specific unless indicated as such.

Responses to questions on specific topics were solicited through a Likert scale (1 = extremely poor, 5 = extremely good). In addition, 15 value statements were presented to the HCPs and patients respectively for maximum-difference (max-diff) scaling. Max-diff uses a series of trade-off exercises to determine the relative performance of each tested item. Respondents were presented with a series of items and asked to indicate which were most or least important to them. A statistical model then produced values for each item, showing the relative importance.

## Literature review<sup>6</sup>

A review of existing literature, including databases, scientific papers and publications, was conducted to determine the extent of literature on the value of clinical research for patients, HCPs and clinical trial centres. Our research spanned the medical literature, the work of consultancies and papers by industry organisations such as the European Federation of Pharmaceutical Industries and Associations and Pharmaceutical Research and Manufacturers of America.

We also sought to determine what pharmaceutical companies have studied in this area. Only three of the top 15 companies have publicly addressed the value of clinical research in more than just general terms. Most have published information on macroeconomic factors, such as job creation, but none have looked at the value of clinical research in a holistic way. No

reports were similar in scope with respect to disease area, country coverage and stakeholders. The reports previously published are either country-specific and/or focus on specific stakeholders. None focus specifically on diabetes.

## Job impact analysis<sup>6</sup>

Direct and indirect job creation estimates are based on macroeconomic input–output models. This report estimates the job-creation effects of the clinical development programmes for liraglutide and the degludec family of products.

Direct job creation refers to jobs created directly by Novo Nordisk in the process of conducting clinical research. Indirect job creation occurs through the impact of conducting research on suppliers and contractors and through subsequent economic activity resulting from private consumption (responding). Indirect job creation is calculated through a multiplier effect. Economic multipliers are generated through the use of input-output models. These are statistical models that quantify inter- and intra-industry relationships. They reveal the pattern of purchases by industries and the associated distribution of jobs and wages by industry. We used the World Input-Output Database (WIOD)<sup>39</sup> to develop valid comparable models for India, the US and Denmark. From this, multiplier effects were calculated for Denmark (3.2), the US (5.0) and India (9.3).

An employment multiplier of 3.2 implies that one extra Novo Nordisk full-time equivalent creates 2.2 full-time equivalents in the rest of the economy.

## GLP-1 capabilities analysis<sup>32</sup>

Method used in the SiteTrove analysis:

- GLP-1 compounds that have completed phase 3
- Exenatide, liraglutide, exenatide extended-release for injectable suspension, lixisenatide, albiglutide, dulaglutide
- Phase = 3 trial sites; Location = the US, DK or India; Drug tested = compound name; Sponsor = owner(s) of the compound
- Each compound is searched individually
- Assumption: EU/US launch order is similar to order of phase 3 initiation

## External review

External reviewers of this Blueprint for Change study:

- Marc Evans, Medical Director, Expert Medical Opinion Limited, UK
- Sebastien Mazzuri, Associate Director, FSG, Switzerland

# glossary

## Clinical trials

Pharmaceutical clinical trials are conducted to determine the efficacy and safety of a medication.

## Contract research organisation (CRO)

Provides outsourced research services for pharmaceutical, biotechnology and medical device companies.

## Diabetes

Diabetes is the common term for several metabolic disorders in which the body no longer produces insulin or uses the insulin it produces ineffectively.

Type 1 diabetes is a lifelong condition that is treated with insulin administered by injection or using an insulin pump. Type 1 diabetes develops when an 'autoimmune reaction' destroys beta cells in the pancreas. An autoimmune reaction means that the body creates antibodies against its own cells. As a result, the pancreas stops producing insulin or cannot produce enough insulin on its own. Treatment involves daily insulin treatment in conjunction with healthy eating and regular exercise.

Type 2 diabetes is a term for several disorders with different causes and degrees of severity. It is the most common type of diabetes. Often, people with type 2 diabetes can still make their own insulin in the pancreas, but the insulin that is produced is not used as effectively by the body. Many people manage type 2 diabetes simply by following a healthy diet and exercising regularly, while others need medical treatment. In overweight individuals, type 2 diabetes often improves as a result of weight loss, a healthy diet and exercise.

## Endpoint

The target outcome of a clinical trial.

## GLP-1

Refers to glucagon-like peptide-1, a type of injectable drug for the treatment of diabetes.

## HbA<sub>1c</sub>

Glycated haemoglobin, which reflects the average plasma glucose concentration over prolonged periods of time. Lowering HbA<sub>1c</sub> to around or below 7% is associated with reduced risk of complications of diabetes.

## Hypoglycaemia

Abnormally low blood glucose levels. Episodes of mildly low blood sugar are common for people with diabetes. Severe hypoglycaemia can lead to seizures, nervous system damage or death.

## Insulin

A hormone that helps the body use glucose for energy. The beta cells of the pancreas make insulin. If the body is unable to make enough insulin, it can be administered by injection or using an insulin pump.

## Journal impact factor

An indication of journal prestige, based on the volume of citations of articles published in the journal in question.

## Multiplier effect

A factor for estimating economic cause and effect, for example job creation resulting from a specific event.

## Panels

Panels, when conducting surveys, are comprised of people meeting certain demographic criteria.

## Patient years

Measured as the total number of months a patient is enrolled in a clinical trial divided by 12. Example: 1,000 patients studied over six months would equal 500 patient-years.

## Screening success

When a patient recruited for a clinical trial meets the criteria for acceptance into the trial. Screening failure refers to when a person who consented to participate in the clinical trial is disqualified as a result of screening procedures.

## Shared value

The realisation of synergies between business and society.

## Specialist

In our survey, a specialist refers to a diabetologist and/or endocrinologist.

## Titration

Incremental increase in drug dosage to a level that provides the optimal therapeutic effect.

## Triple Bottom Line

Novo Nordisk's business principle of balancing financial, social and environmental considerations.

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GET IN TOUCH

**Peter Kristensen**

Senior Vice President, Global Development

**Ole Kjerkegaard Nielsen**

Programme Director, Corporate Sustainability

[sustainability@novonordisk.com](mailto:sustainability@novonordisk.com)

## The **Blueprint for Change** Programme

The Blueprint for Change Programme is a series of case studies of how Novo Nordisk creates shared value with its Triple Bottom Line approach. The case studies speak with data and are based on extensive field research and a common methodology for value creation. Each Blueprint for Change case study seeks to strengthen the link between our approach to sustainability and its related value creation, highlighting successes and exploring challenges ahead and ways to improve.



The **Blueprint for Change** Programme  
[novonordisk.com/blueprint](http://novonordisk.com/blueprint)

### About Novo Nordisk

Headquartered in Denmark, Novo Nordisk is a global healthcare company with 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. We believe that a healthy economy, environment and society are fundamental to long-term value creation. This is why we manage our business in accordance with the Triple Bottom Line business principle and consider the financial, environmental and social impact of our business decisions. The strategic commitment to corporate sustainability has brought the company onto centre stage as a leading player in today's business environment, recognised for its integrated reporting, stakeholder engagement and consistently high sustainability performance. For more information, visit [novonordisk.com/sustainability](http://novonordisk.com/sustainability)

