SYNEXUS

The patient's choice for clinical research

IBDconnect

Bringing your study to IBD patients and their physicians

Challenges in IBD clinical research

The IBD clinical trial challenge is considerable. Clinical research in Inflammatory Bowel Disease (IBD) is an exceptionally competitive market.

There are a limited number of active GI research sites, many of which are inundated with trials. There are a limited number of potential trial subjects within the active research sites. IBD trials often require a disease flare or specific inclusion / exclusion requirements.

As a result, there is a large backlog of IBD trials accumulating from multiple developers, and randomised patients can be very expensive.

- Numerous competing studies
- Insufficient access to patients
- Limited number of investigators
- Challenging protocols

A solution is needed to augment the enrolment.
That solution is IBDconnect.

Experience matters

Synexus is uniquely qualified to offer such a solution. Rather than rely exclusively on active research sites to source patients, we bring a sponsor's IBD study to patients and their own GI specialty physicians.

Since 1992, we have consistently helped sponsors meet their enrolment goals by gaining access to patients of research-naïve practices in close proximity to Synexus dedicated research sites. We subcontract the physicians' practices and provide our own dedicated clinical trial services to these physicians – a methodology that we have perfected throughout years of experience and across more than 400 indications. In this model, Synexus is 100% focused on the conduct of research within the subcontractor practice. As a result, we produce quality data for our pharmaceutical sponsors, provide superb care to the practices' patients, and make research extremely efficient for the subcontracted practice.

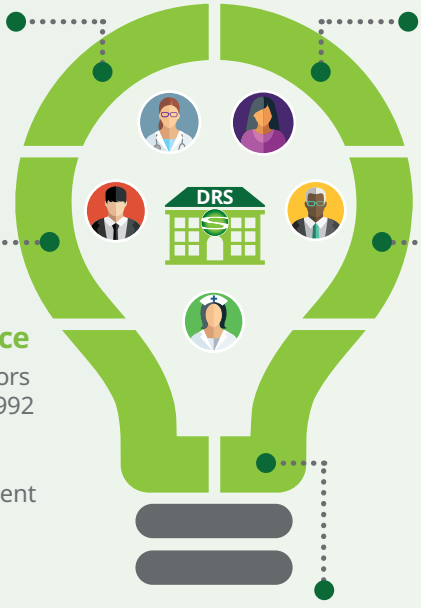
The IBDconnect model is scalable and is readily available for IBD trials. Our physician networks and contacts are well-established. We have vendors in place that can be used for specialist procedures as required. And, because our site network infrastructure is already in place with trained clinical research experts at the ready, a global IBD pilot or full-scale programme can be up and running in approximately four to six months.

Increased patient reach

By gaining access to GI specialty practices in close proximity to Synexus dedicated research sites, we can bring the IBD study to patients and their own GI physicians

Benefits for all stakeholders

100% focused on research within subcontracted practices, producing quality data for sponsors, providing superb care to patients, and making research efficient for subcontracted practices



26+ years of broad experience

We have consistently helped sponsors meet their enrolment goals since 1992 across more than 400 indications – experience that includes the implementation of patient recruitment models like IBDconnect

Well-established network

Our physician networks and contacts are well-established, and we have vendors in place that can be used for specialist procedures as required

Scalable model readily available

Because our site network infrastructure is already in place with trained clinical research experts at the ready, a global IBD pilot or full-scale programme can be up and running in approximately four to six months

The IBDconnect solution
How it works

The following is an overview of IBDconnect, the Synexus IBD clinical trial solution. Ultimately, the final design of the programme is dependent on factors such as protocol design and requirements, the study scope, and the required country reach.

Partnering practices with IBD patients

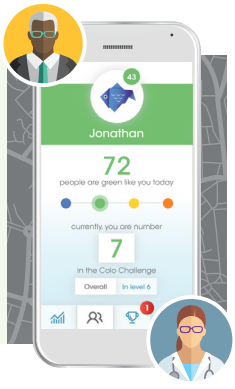
First, we identify and recruit interested and qualified GI practices as subcontractor research sites. All practices will be in close proximity to an established Synexus dedicated research site (DRS) clinic.

The Synexus DRS network currently consists of 57 dedicated clinics spanning 11 countries, including Bulgaria, Czech Republic, Germany, Hungary, Poland, Romania, South Africa, UK, and US. In the US, newly recruited GI practices, as well as existing integrated sites with GI physicians, will be used.

Outside the US, a hybrid approach will include the use of our integrated and/or affiliated site setup model, our established referral network of healthcare professional partners, and vendors used to conduct specialist procedures and assessments. This approach will depend on a number of factors, including the existing Synexus clinic infrastructure, the established existing referral network in place, and the healthcare structure in that country.

Meetings will be held with targeted GI specialists to determine their level of interest and experience in clinical research, existing capabilities and limitations in conducting IBD trials, typical patient population, and potential access to IBD patients including local database accessibility.

All participating GI practices and their pre-screened patients will be provided with both virtual and traditional methods for identifying IBD flares or other study-related criteria across their GI clinical patient populations. Patients who prefer the virtual method can download our **COLO Flare app**. It keeps potential patients actively engaged until flare symptoms emerge, then notifies them to discuss study participation with their specialist physician. Patients who are unable to or choose not to use the virtual approach will be educated to return during flare up via traditional methods.



Support in research

Once a local practice is contracted, a mobile team of clinical research experts from the nearby Synexus DRS clinic will travel to the practice at regularly scheduled times to conduct trial-related activities throughout the duration of the study. The Synexus team will include personnel such as a Clinical Research Nurse, Data Manager, Research Physician, and other staff as needed to support the GI specialist team. The GI practice will undergo training on Investigator Responsibilities, Good Clinical Practice, Good Documentation Practice, Synexus procedures, the trial protocol and any other study-specific materials that are necessary for the study.

To minimise the administrative and staffing burden for the subcontractor practice, the Synexus experts will conduct pre-defined tasks of the clinical trial, such as EDC and ISF management, non-specialist visit assessments, patient visit scheduling, and IP management. Additional services may be utilised depending on the requirements of the sponsor, the study, and the GI specialist team.

Screening visits can either be done at the practice or at the nearby Synexus site. The GI specialty physician may or may not be included, depending on the nature of the program and the specialist's preference. The GI practice will receive revenue for any procedures, endoscopies, and specific evaluations for the study that it performs. Whether the Synexus DRS or the GI practice is identified as the main study clinic will be pre-determined in the contractual agreement.

Synexus support network

Our unique IBDconnect solution benefits all stakeholders

By connecting IBD patients and their physicians to local studies, IBDconnect delivers important benefits for all constituents.

GI practices

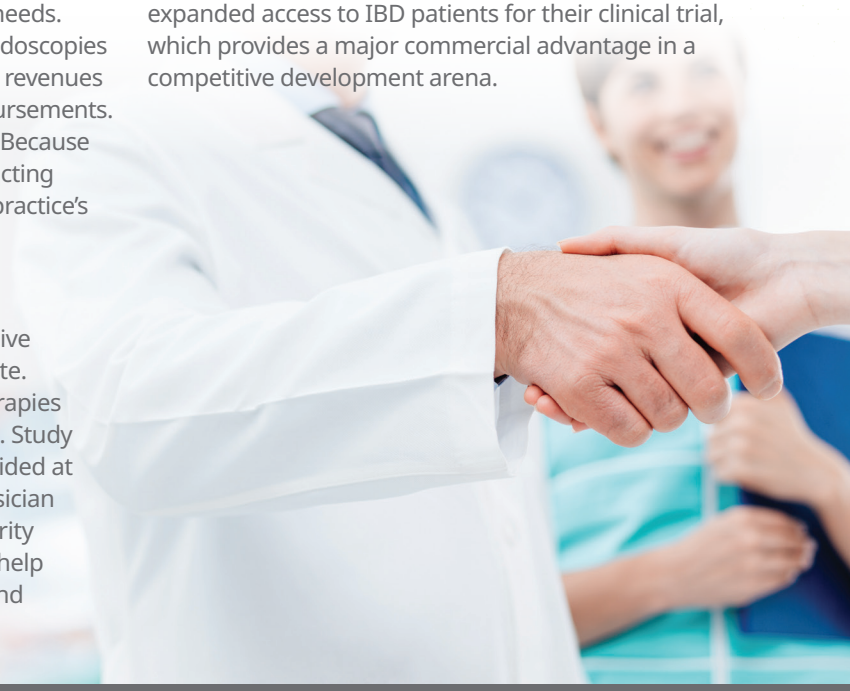
GI subcontractor practice physicians don't lose their IBD patients to another clinical research site. They gain access to an investigational drug, giving them the opportunity to offer their IBD patients additional therapies that may address unmet medical needs. When a physician performs study-related endoscopies and other procedures, their practice accrues revenues that are often greater than insurance reimbursements. Physicians gain clinical research experience. Because the Synexus team is 100% focused on conducting the trial, there is virtually no increase in the practice's administrative burdens or staff.

Patients

IBD patients in the GI specialty practice receive additional education about their disease state. Their physicians gain access to new IBD therapies that may address their unmet medical need. Study medication and study-related visits are provided at no cost. They are able to stay with their physician whom they know and trust. Patients' familiarity with practice staff, hours, and location may help to increase their willingness to participate and remain in the study.

Trial sponsors

IBD clinical trial sponsors gain access to new and available investigator sites and their IBD patients, while utilising the expertise of established Synexus clinical research teams. They receive rapid and expanded access to IBD patients for their clinical trial, which provides a major commercial advantage in a competitive development arena.



IBDconnect

Synexus has the track record of success, turnkey infrastructure, clinical research experts, and capacity to implement such a solution to the high-demand arena of IBD trials.

Synexus can partner with you immediately in the planning and execution of a successful IBD clinical trial. Contact us today to schedule an introductory meeting.

To find out more about IBDconnect and opportunities in clinical trials, please email our Chief Medical Officer, Dr. Dawie Wessels.

Email **dawie.wessels@synexus.com** | Visit **synexus.com**

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