

# INSIGHTS

## Nutritional CRO: Bowel function



BioTeSys

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**Key words:** bowel function, clinical trials, gastrointestinal discomfort, nutritional supplements, SmartPill®, stool consistency, stool frequency, stool weight, transit time

**Bowel function** Constipation is one of the most common health impairments in Western countries. Its prevalence is widely variable, depending on criteria utilized for diagnosis. Usually constipated patients have mild to moderate symptoms which are predominantly self-treated. For that reason the digestive tract and its function are promising targets for functional foods and dietary supplements. But what is the definition of a healthy gut or its normal function? And how can this be assessed?

The answer: stool frequency, stool consistency, stool weight and transit time as well as parameters of gastrointestinal discomfort.

In recent years, multiple studies with focus on bowel function and gastrointestinal well-being have been successfully conducted by BioTeSys. Thereby, the following methods are on hand:

**Stool frequency** Most adults in Western countries have on average one bowel movement per day, passing between three a day and three a week. Subjective grading by those affected contrasts strongly with the formal definition of "normal" bowel habits. Commonly not having daily bowel movement is equated with suffering from constipation. Actual bowel movements can conveniently be recorded using a bowel habit diary.

**Stool consistency** The consistency is recorded in a diary after visual inspection. Helpful is the Bristol Stool Form Scale which defines stool types. Types 1 and 2 indicate constipation, with 3 and 4 being the ideal stools (especially the latter), as they are easy to defecate while not containing any excess liquid, and 5, 6 and 7 tending towards diarrhoea.

**Stool weight** Based on our experience, determination and documentation of total stool wet weight could be managed by subjects at home using a standardized stool kit (commercially available) and scale without decrease of validity. Additionally, subjects' compliance is very high using this method compared to different techniques.

Furthermore, for determination of stool dry weight subjects collect a small sample from the total stool and store it at -20°C until next visit.

Based on our knowledge, effects of products supporting bowel function are less pronounced in stool dry weight. Therefore we suggest analyzing stool dry weight depending on results of total wet weight.

**Transit time** Commonly radiography is suggested to document total transit time. We rate the measurement of total transit time by radiography as a crucial point for two main reasons. At least in Germany the use of radiography will lead to a significant increase of time, because an additional approval from the Federal Office of Radiation Protection will be obligatory. Furthermore, due to a lack of acceptance to radiation exposure, a higher effort for the recruitment of subjects will be presumable.



To avoid these difficulties the SmartPill® motility monitoring system could be a suitable option. SmartPill® is an ingestible capsule that simultaneously measures the gastrointestinal (GI) and colonic pH, temperature and intraluminal pressure. Even if this method is linked with higher costs, SmartPill® can be used to measure whole gut transit and also regional GI transit through identification of characteristic changes in pH profile down the GI tract (i.e. abrupt rise in pH on exiting the stomach and rapid drop in pH from alkaline to mildly acid on passage through the ileocecal region).

SmartPill® technology is sensor-based and therefore eliminates radiation exposure.

**Gastrointestinal discomfort** The subjective rating of gastrointestinal discomfort and of course gastrointestinal well-being should not be underestimated. For this purpose validated questionnaires containing items like bloating, abdominal pain or flatulence can be used.

**Statistical Analysis** As there is no single symptom or parameter which clearly reflects the constipation phenomenon - especially in only mildly constipated subjects - a smart option is considering a combination of an adaptive statistical design with multidimensional endpoints (e.g. bowel function parameter and global assessment). Thereby the key advantages of a pilot trial are combined with those of a confirmatory study while avoiding the disadvantages. The approach is FDA approved and accepted by EMA.

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**Nutritional CRO & Study site** We consider ourselves as a nutritional CRO with profound expertise and longstanding, international experience in nutrition-related questions involving bioactive ingredients. The interdisciplinary team offers valid strategies to cover customer needs. The precise implementation in our in-house testing centre enables the verification of concepts, the detection of health related effects and the scientific substantiation of health claims for market communication.

In order to guarantee highest quality our internal QM system based on ICH-GCP is established.

*Please feel free to contact us if you have any questions. We would be happy to prepare an outline on your demand.*

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