Pillcam technique helps the design of the oral formulations

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- **Background**: Existing procedure(s) Conventional Endoscopy has been used to examine the dissolution and disintegration of tablets in anaesthetized dogs.

- **Description of initiative**: Pillcam capsule endoscopy is an orally dosed, non-invasive capsule equipped with two miniature cameras at both ends. The capsule is able to visualize tablet disintegration/dissolution in the GI-tract of conscious dogs with limited disturbance, which allows for a physiological relevant model with minimal unpleasantness for the animals.

- **Reason for initiative**: The direct real-time visualization of tablet dissolution and disintegration \textit{in vivo} obtained by the pillcam capsule endoscopy would greatly help understand the behaviour and the MOA of different oral formulation concepts. The \textit{in vivo} dissolution data can potentially be used for the development of predictive \textit{in vitro} models, in that case it can reduce the need for corresponding animal studies to some extend in the future. Therefore, all these findings would strongly support a more rational development of oral formulations.

- **Impact of initiative**
  - **Which animals are affected?**
    Beagle dogs are affected at the moment. But it is applied to pigs and NHPs theoretically.
  - **How many animals are affected?**
    Not an accurate animal numbers could be estimated at the moment. But we would expect an estimation of about 25% large animal studies, especially formulation related studies could be reduced.
  - **Future implications for Novo Nordisk**
    Novo Nordisk would gain more knowledge from the animal studies with pillcam, which would potentially lead to a more clear direction on formulation design. Based on it, less relevant animal studies would be needed in the future.
  - **Future implications for science in general**
    The Pillcam visualization of \textit{in vivo} formulation behaviour allows for the establishment of a relationship between formulation properties and the pharmacokinetic features of different types of oral formulations. This will in turn lead to the development of better \textit{in vitro} models, faster development times and a reduction in animal studies needed for formulation optimization.

- **Do you intend to publish or in other ways share with external stakeholders?**
  Yes, we do.