NanoBreath:

Affordable detection of *Helicobacter pylori* in the developing world

What?

mucous layer ———

inflamed epithelial cells
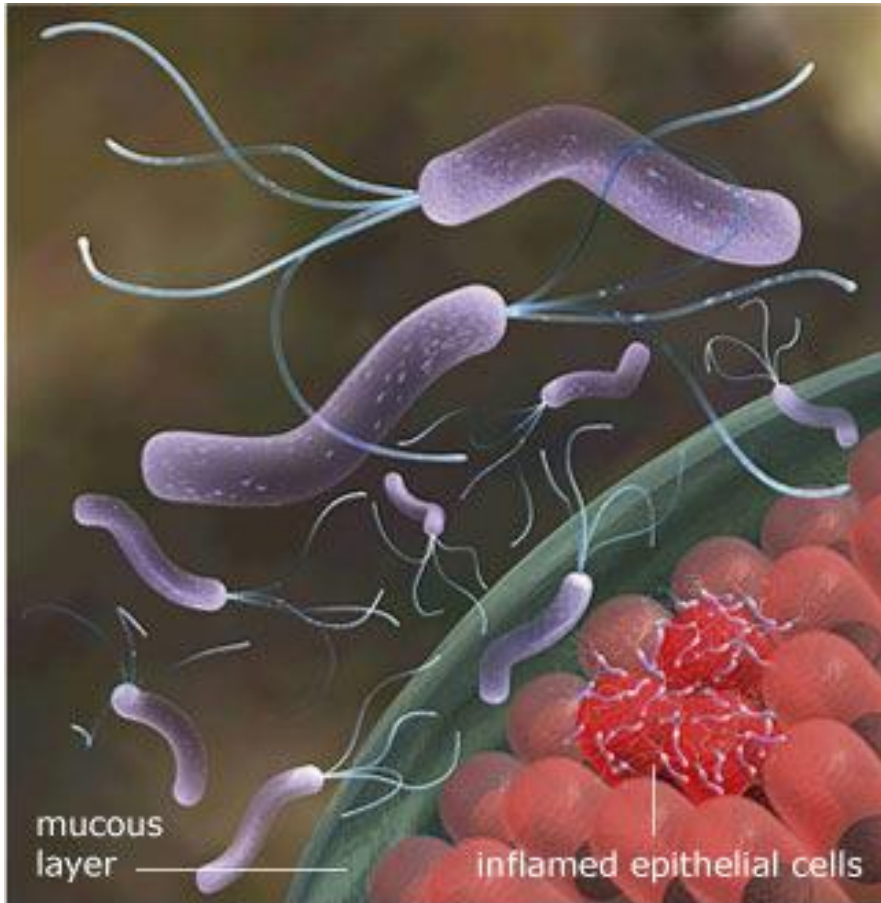
- *Helicobacter pylori* is one of the most common bacterial infections

- Spiral-shaped bacterium that infects well over 30% of world's population

- About 40% of people in the UK have the bacteria in their stomach

- Higher infection rates correlate with: crowded living conditions, poor sanitation/personal hygiene/water supply (~ 80% in developing world).

- Most infections occur in childhood.

Why?

ulcer

layer of mucus
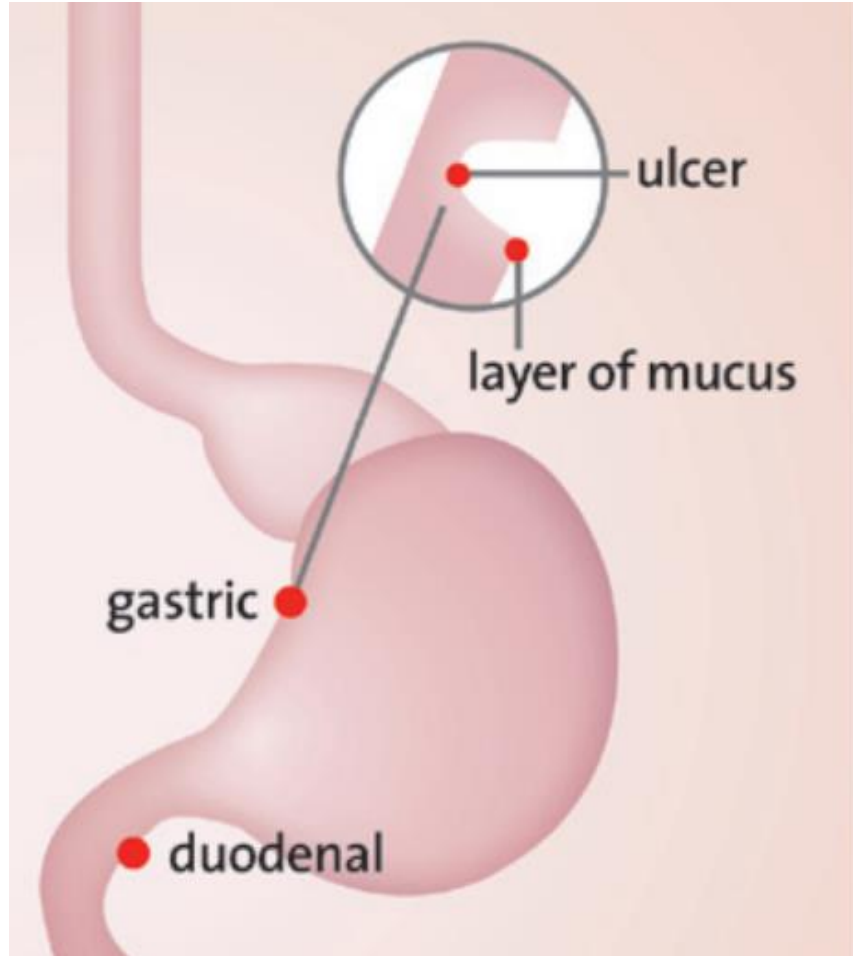
gastric

duodenal

- It invades the mucosal lining of the stomach and is the cause of up to 95% of duodenal and up to 75% gastric ulcers and has also been associated with gastric cancer and lymphoma

- About 15% of people with *H. pylori* infection get ulcers either in the stomach or in the duodenum

- Ulcers tend to cause indigestion, they can bleed or even burst (perforate) which happens if the ulcer burrows deep enough to make a hole

- World Health Organisation has declared the bacteria to be a Class 1 carcinogen (1 to 3% of those infected will develop distal gastric adenocarcinoma)

How big an issue?

Estimated size of the patient populations presenting in our principal territories

| Country/ Region	Population	*H. pylori* Prevalence	Infected population	Number of patients (1% annual presentation with symptoms)
India	1,211 million	80%	967 million	9.7 million
China	1,344 million	80%	1,075 million	10.8 million
Brazil	201 million	80% estimate	161 million	1.6 million
Total				*22.1 million*

Solution: An affordable Urea Breath Test (UBT)
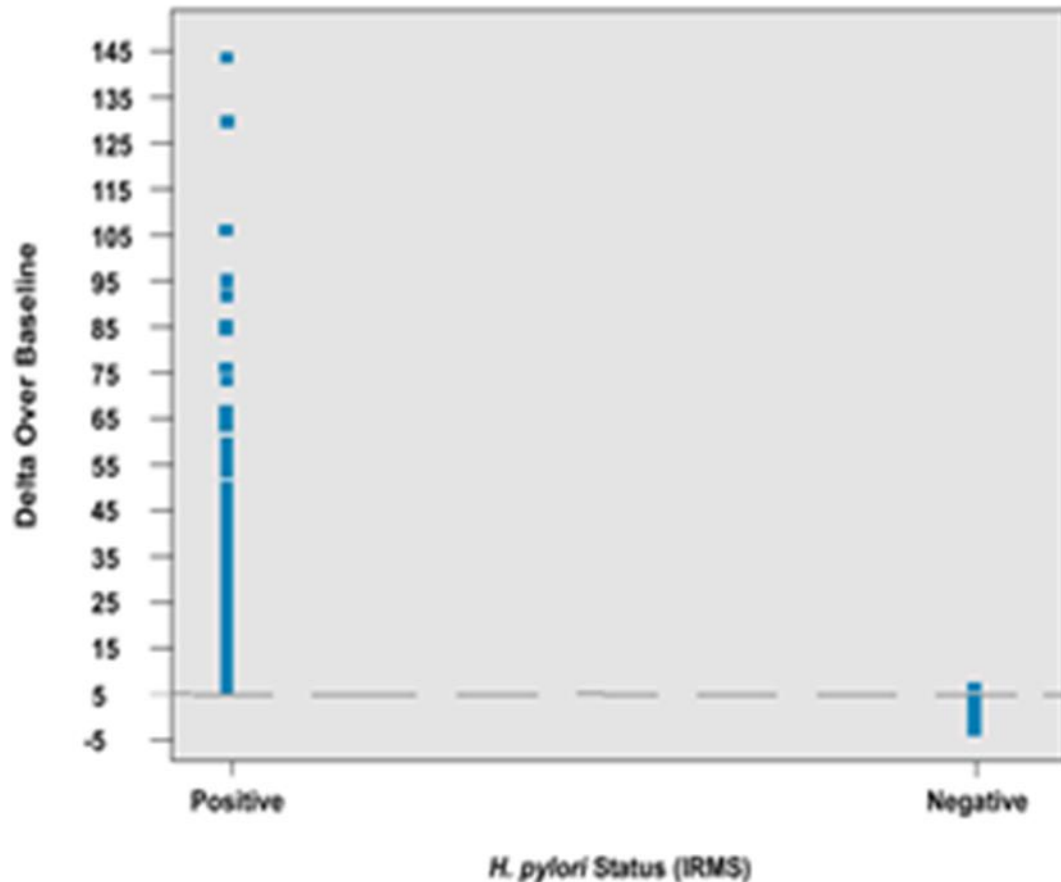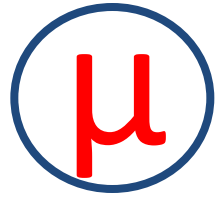
*Soure: Oridion Medical 1987 Ltd Clinical Study(NDA 21-314)*

1. A baseline patient breath sample is collected and the $\delta^{13}C$ (‰) of their CO_2 determined

2. The patient then swallows a $\delta^{13}C$ labelled urea pill

3. If present then *H. pylori* will metabolise the urea resulting in a positive shift in $\delta^{13}C$ (‰) of the CO_2

4. Patient's breath is re-collected ~ 20 minutes after the labelled urea pill is taken

5. A delta-over-baseline (DOB) shift in the $\delta^{13}C$ of > 10 ‰, between the two patient samples, is considered a positive sample
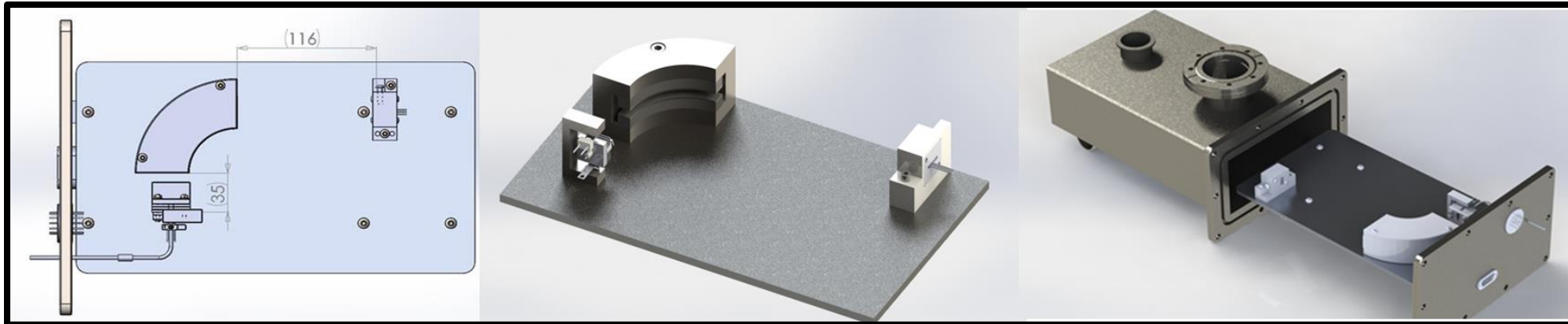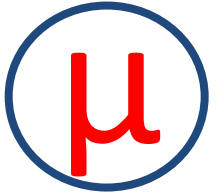
Link to Space?
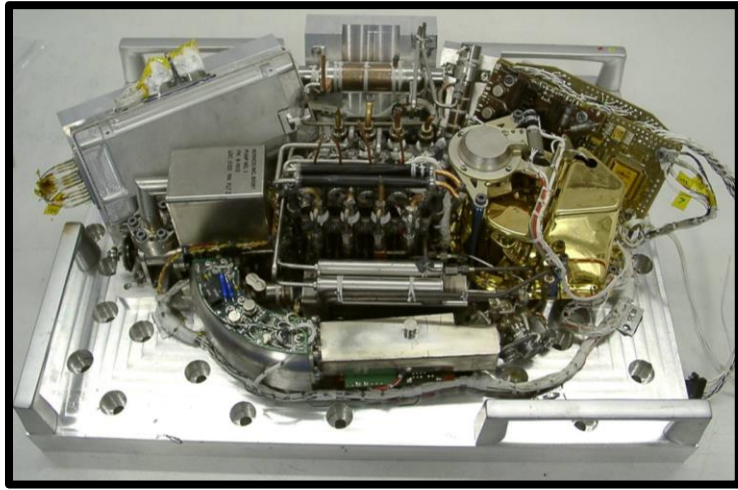
Gas Analysis Package on Beagle2
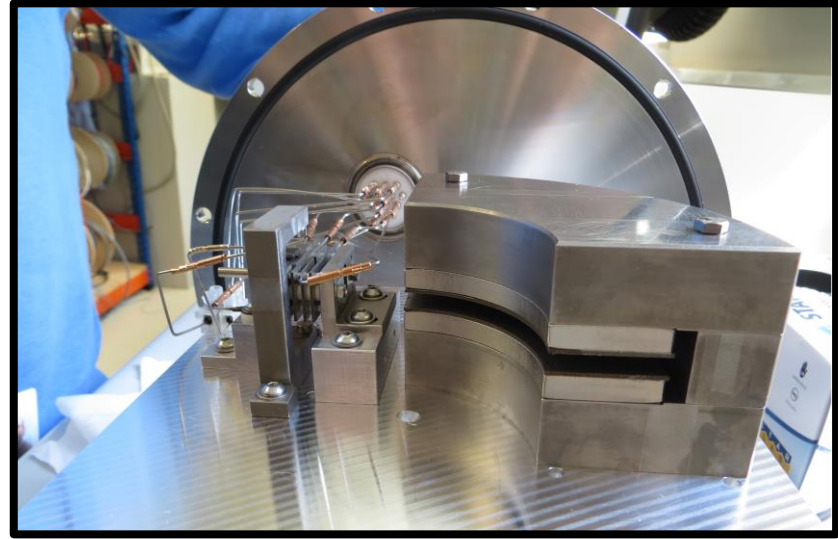
NanoBreath Prototype

NanoBreath Final Product Philosophy

The Road to Market

1. **Regulatory Compliance Support**
   - Access to Regulatory Body appropriate for the target region
   - Medical Classification
   - CE Marking
   - Technical File Support

2. **Design for Manufacture**
   - Electronic PCBs and harnessing
   - Enclosure and internal architecture
   - Packaging

3. **Manufacture, Assembly and Integration of Production Product**

4. **Design for Test**
   - Test solution for production product - minimising time, cost and skill set yet accurate and reproducible acceptance testing

5. **Accessory Management**

6. **Warehousing / Logistics / Shipping & Distribution**

7. **Post Product Support**
   - Servicing
   - Warranties
   - Repair/maintenance
   - Rental Support