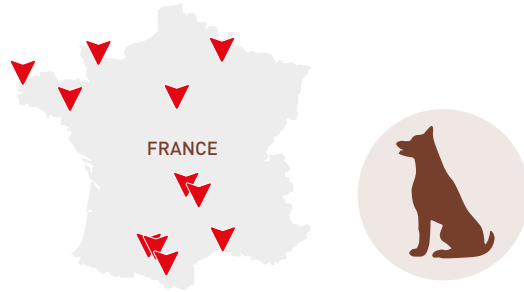




## VETERINARY CLINICS INVOLVED

The objective of this field study was to evaluate the performance of the new ROYAL CANIN® GASTROINTESTINAL LOW FAT + HYPOALLERGENIC canine dry veterinary diet in a practice setting.

The study took place in France; 11 companion animal veterinary clinics returned a total of 14 completed cases.



## TRIAL PROTOCOL

### SELECTION CRITERIA

#### INCLUSION:

- Adult dogs with a gastrointestinal disorder
- Dewormed and treated against external parasites (fleas, ticks, etc.),
- With an adapted Canine Chronic Enteropathy Clinical Activity Index (CCECAI) (excluding albumin) ≥ 5
- Chronic enteropathies: with soft or liquid stools at least twice a week for at least 2 weeks and one or more of the following signs: increased frequency of stools - increased volume - vomiting
- OR Recurrent enteropathies: with soft or liquid stools and one or more of the following signs: increased frequency of stools - increased stool volume -vomiting AND that already consulted for soft or liquid stools at least once within the past year (except if the GI disorder was caused by the consumption of inappropriate elements by the pet, stress or concomitant disease known)
- No current medication.

Animals previously medicated under one or more protocols (anti-inflammatory, antibiotic) that did not fully respond to treatment were authorized.

#### EXCLUSION/WITHDRAWAL:

- Severe concurrent disease
- Eating refusal, insufficient food consumption (<80% daily ration over 3 days)
- Worsening of symptoms during trial
- Use of prohibited drugs
- Undesired weight loss in excess of 15%.

### INTERVENTIONS

Nutritional management (= test diet only, no additional drug) was preferred, but some medications were left at the vet's discretion to reflect normal practice.

#### PROHIBITED MEDICATIONS:

- Short-term and long-acting (injectable or oral) steroids
- Essential fatty acid supplements, antibiotics treatments, parenteral antiemetics
- Oral antiemetics, after food transition.

#### AUTHORIZED DURING THE STUDY, IF DEEMED NECESSARY BY THE VET:

- Interventions with no impact on GI tract: shampoos, ear cleansers, ear drops, external antiparasiticide application, etc.
- Vitamin B9 and B12 supplementation.

### POPULATION CHARACTERISTICS

DESCRIPTION OF COMPLETED CASES	
NUMBER	14
SEX & NEUTERING STATUS	11 Males (5 neutered, 6 intact) 3 Females (3 spayed)
AGE AT V0: MEAN (RANGE)	4.1 years (1-12 years)
BODYWEIGHT AT V0: MEAN (RANGE)	27.0 kg (6.9-41.0 kg)
BODY CONDITION AT V0	Thin to overweight
BODY CONDITION SCORE (BCS) V0	2 [1-6%]; 3 [4 [23%]]; 4 [2 [12%]]; 5 [9 [53%]]; 7 [1[6%]]
CCECAI AT V0: MEAN (RANGE)	6.9 [5-12]

## TRIAL PROTOCOL

### STUDY DESIGN



PREVIOUS DIET → ROYAL CANIN® GASTROINTESTINAL LOW FAT + HYPOALLERGENIC

V0 V S1 V S2

### ASSESSMENT OF THE EFFICACY OF THE DIET

#### BY THE VET (V0, VS1 AND VS2):

- Physical examination including dog's body weight and BCS (Body Condition Score)
- Gastrointestinal discomfort signs evaluation: presence or absence of diarrhea, vomiting, melena or hematochezia, fecal mucus, abdominal pain, tenesmus, abnormal behavior, or any other GI-related clinical sign
- Gastrointestinal disorders evaluation scale (calculated from validated Canine Chronic Enteropathy Clinical Activity Index (CCECAI)).

#### BY THE DOG OWNER (V0, PC, VS1, VS2):

- Scoring of digestive signs: appetite, vomiting/nausea, stool consistency, stool frequency, pain/discomfort
- Scoring of quality of life (QoL): score from 1 = very deteriorated to 10 = very good
- Scoring the owners' perspective of the impact of the animal's condition on their own routine. Score from 1 = not at all bothersome to 10 = extremely bothersome.

- Inclusion visit (V0), at day 0: full clinical examination by the vet including blood sampling and completion of GI questionnaire
- Follow-up phone call at day 7: follow-up/collection of owner observations on symptoms evolution
- Follow-up vet visit at 1 month (VS1): follow-up/collection of owner observations on food consumption and vet clinical examination for symptoms evolution
- Final visit (VS2) at 2 months: same as VS1 + evaluation of product efficacy.

### CLINICAL ACTIVITY INDEX (CCECAI)

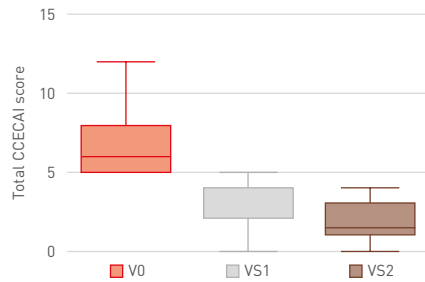
CLINICAL SIGNS	SCORING
ATTITUDE / ACTIVITY	0 = normal 1 = slightly decreased 2 = moderately decreased 3 = severely decreased
APPETITE	0 = normal 1 = slightly decreased 2 = moderately decreased 3 = severely decreased
VOMITING	0 = normal, no vomiting 1 = mild vomiting (1x/week) 2 = moderate vomiting (2-3x/week) 3 = severe vomiting (>3x/week)
STOOL CONSISTENCY	0 = normal 1 = slightly soft stools 2 = very soft stools 3 = watery diarrhea
STOOL FREQUENCY	0 = normal 1 = slightly increased (2-3x/day) or fecal blood, mucus or both 2 = moderately increased (4-5x/day) 3 = severely increased (>5x/day)
WEIGHT LOSS	0 = none 1 = mild (<5%) 2 = moderate (5-10%) 3 = severe (>10%)
ALBUMIN	0 = albumin >20g/L 1 = albumin between 15-19.9 g/L 2 = albumin between 12-14.9 g/L 3 = albumin <12g/L
ASCITES & PERIPHERAL EDEMA	0 = none 1 = mild ascites or peripheral edema 2 = moderate amount of ascites/peripheral edema 3 = severe ascites/pleural effusion and peripheral edema
PRURITUS	0 = no pruritus 1 = occasional episodes of itching 2 = regular episodes of itching, but stops when dog is asleep 3 = dog regularly wakes up because of itching



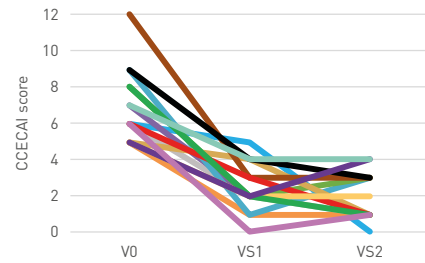
## TRIAL RESULT

### VET ASSESSMENT

- ✓ **Gastrointestinal (GI) disorder:** All the dogs had a decrease of their score and 57% reduced the clinical index activity score by 75% or more after 2 months (Fig. 1 & 2).

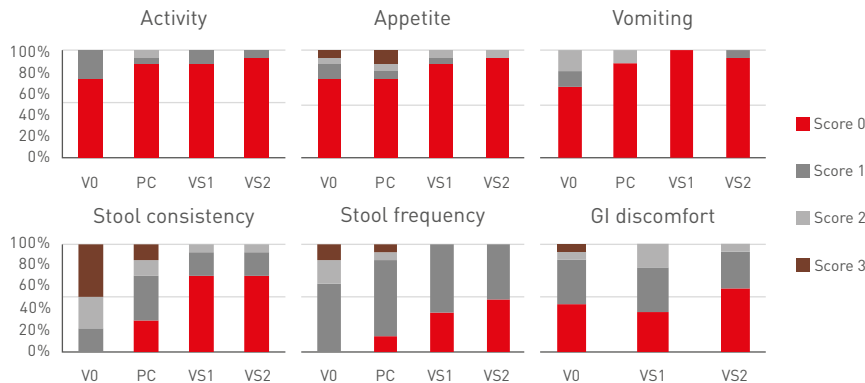


**Fig. 1:** Results from GI disorder evaluation scale (median and 25th and 75th percentiles)



**Fig. 2:** Individual evolution of CCECAI score

- ✓ **Clinical signs:** Almost all the parameters of the CCECAI score improved for all dogs. Normal score (0) was higher for all parameters at VS2 than V0 (Fig. 3).



**Fig. 3:** Results of the main parameters of CCECAI score (percentage of dogs presenting each score).

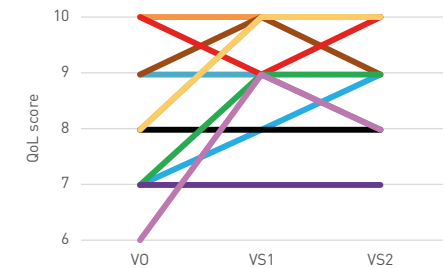
- ✓ **BW:** evolution from -8 to +8%.

- ✓ **Palatability:** All dogs readily ate the diet during the study.

### PET OWNER ASSESSMENT

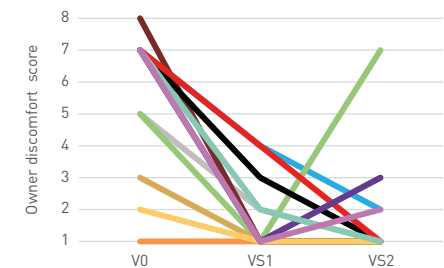
- ✓ **GI signs:** improvement or resolution of GI signs were reported for all dogs but one that completed the 2 months trial.

- ✓ **Quality of Life (QoL):** Most dog owners did not report a decreased Quality Of Life at beginning of study. But 57% of pet owners already reported an improved QoL after 1 month (Fig. 4). Mean score from 8.4 at V0 to 9.0 at VS2.



**Fig. 4:** Individual evolution of QoL (owner perception). QoL score decreases when QoL is altered.

- ✓ **Owners' viewpoint:** 86% of pet owners that completed the 2 month trial reported that the bothersome induced by their pet's condition on their daily life were reduced after the trial (Fig. 5). Mean score from 5.4 at V0 to 1.9 at VS2.



**Fig. 5:** Individual evolution of owners' view on the impact of their animal's condition in their daily life. Owners' discomfort score increases when their pet's health is altered.

### ADDITIONAL RESULTS

- ✓ **Vet satisfaction & diet efficacy:** 93% of vets with patients in this study were satisfied with the diets.
- ✓ **Pet owner satisfaction & intention to repurchase:** Pet owner satisfaction with the diet was rated good to excellent in 93% of dogs. 86% of pet owners said that they would purchase the diets if commercially available.