

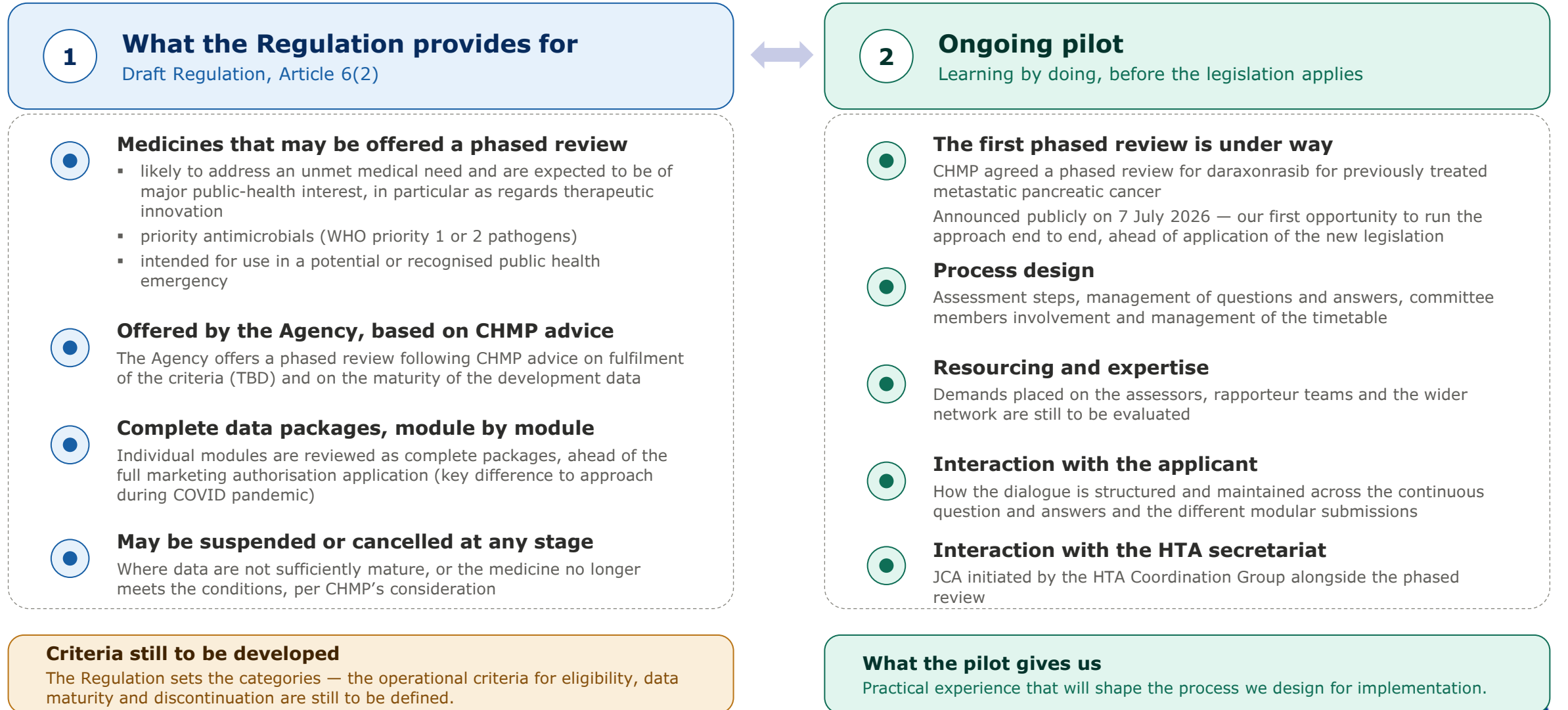
03. Agency phased review process

Francesca Day, Head of Therapeutic Areas,
18th ISG (21/06/2026)



Phased review

What the Regulation provides for, and what the first pilot is teaching us



Why daraxonrasib?

RASolute 302 · phase 3 · 500 patients with previously treated metastatic pancreatic ductal adenocarcinoma · plenary session, 31 May 2026

The disease

Pancreatic cancer in the EU

- around 47,800 new cases and 47,100 deaths a year (EU-27, 2020)
- the fourth leading cause of cancer death
- fewer than one patient in ten survives five years

Two decades of limited progress

- chemotherapy has remained the only systemic option
- no therapy has targeted RAS, the driver in around 90% of cases

≈ 1 min

standing ovation in the plenary hall as the survival data were presented

RASolute 302 — what was presented

13.2

months median overall survival, against 6.6 months on chemotherapy

Hazard ratio 0.40 (95% CI 0.30–0.54); $p < 0.0001$

60%

reduction in the risk of death versus investigator's choice chemotherapy

Primary endpoint met in both the RAS G12 and overall populations

7.3

months median progression-free survival, against 3.5 months

Hazard ratio 0.45 (95% CI 0.34–0.59)

33.2%

objective response rate, against 11.8% on chemotherapy

Confirmed responses by investigator assessment

53.3%

alive at twelve months, against 18.7% on chemotherapy

RAS G12-mutant population

1.2%

discontinued because of an adverse event, against 11.2%

Grade ≥ 3 treatment-related events: 61.8% versus 69.6%

Also reported

Patients were randomised to daraxonrasib 300 mg once daily or investigator's choice chemotherapy. In the overall population, median overall survival was 13.2 against 6.7 months (hazard ratio 0.40; 95% CI 0.30–0.53). Time to deterioration in pain and in global health status was significantly longer with daraxonrasib.

Sources: RASolute 302, late-breaking plenary (LBA5), ASCO Annual Meeting, 31 May 2026 — figures for the RAS G12-mutant population unless stated · EU disease burden: ECIS, Joint Research Centre (EU-27, 2020)



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