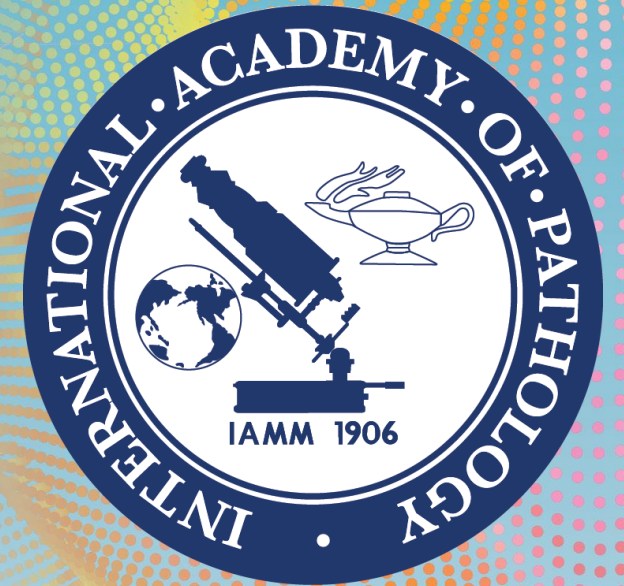


Complete pathological response following levonorgestrel intrauterine device in early-stage endometrial cancer – Results of the feMMe trial

Eva Baxter

University of Queensland



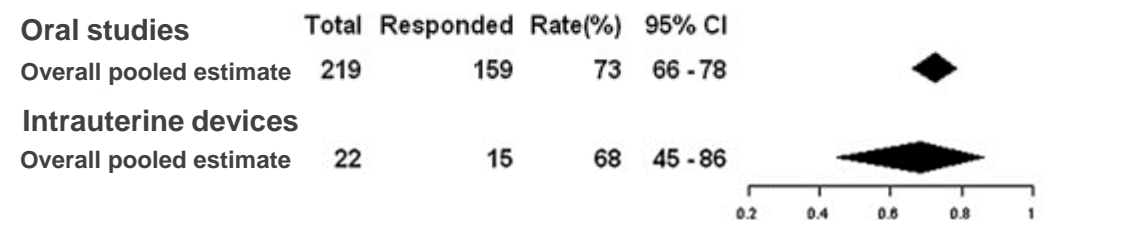
Disclosure of Relevant Financial Relationships

No relevant financial relationships

Background

- Standard treatment of endometrial adenocarcinoma (EAC) is total hysterectomy, BSO ± surgical staging
- This is challenging for two groups of patients:
 1. Young women of childbearing age who wish to preserve fertility capacity
 2. Elderly (frail) women with multiple medical comorbidities who are at high risk of surgical-related adverse events

- Progestins offered *ad hoc* to patients who refuse or are not suitable for surgery
- Robust evidence is lacking

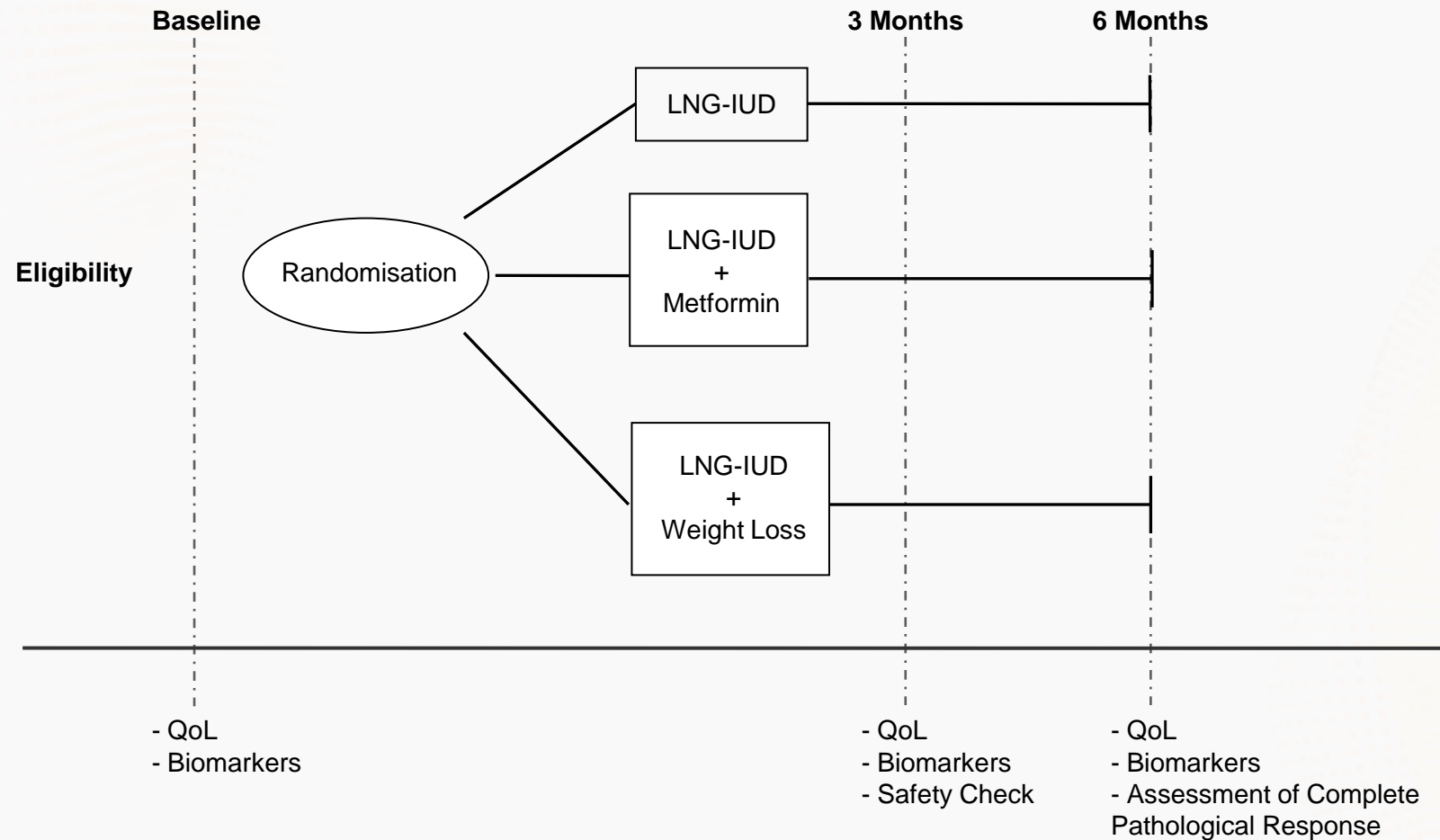


Baker *et al.* Gynecol Oncol 2012

feMMe trial (NCT01686126)

Title	A Phase II Randomised Clinical Trial of Mirena® ± Metformin ± Weight loss Intervention in Patients With Early Stage Cancer of the Endometrium
Design	Open label, randomised, phase II trial
Setting	16 hospitals in Australia and New Zealand
Participants	165 females with complex endometrial hyperplasia with atypia (EHA) or grade 1 endometrioid endometrial adenocarcinoma (EAC)
Intervention	LNG-IUD (Mirena®) ± Metformin or Weight loss
Primary outcome	Pathological complete response at 6 months
Secondary outcome	Predict response to treatment

Trial schema



Inclusion & exclusion criteria

Inclusion criteria

- >18 years of age
- Histologically confirmed EHA or FIGO grade 1 endometrioid EAC
- Desire to maintain fertility or at high risk of surgical complications due to severe medical comorbidities
- Clinical stage 1
- MRI with depth of invasion <50%
- BMI >30kg/m²
- CA125 ≤30U/mL

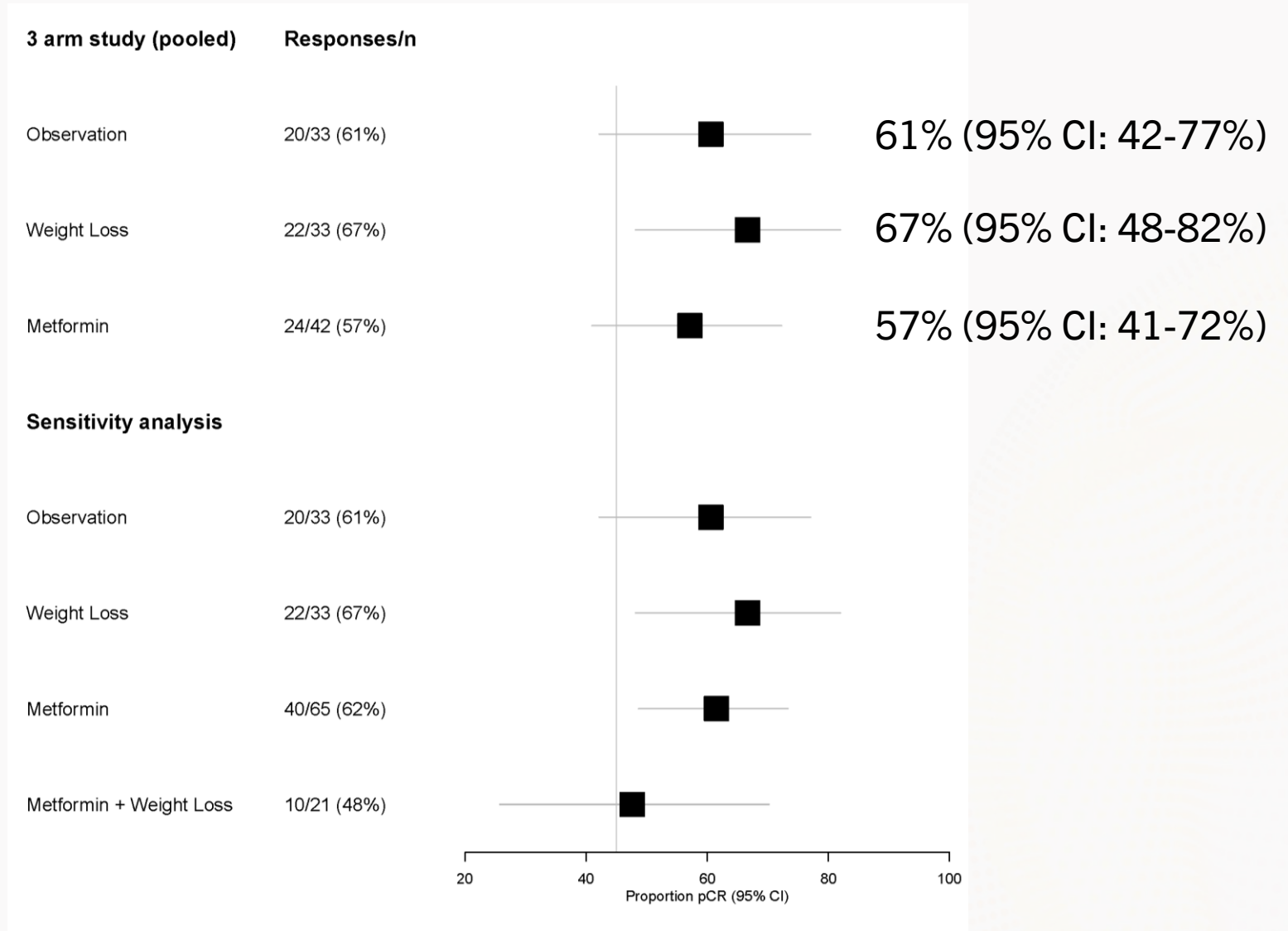
Exclusion criteria

- ECOG >3
- FIGO grade 2 or 3 EAC, high-risk cell types
- Previous treatment with progestins (<12 weeks before enrolment)
- History of pelvic/abdominal radiotherapy
- Acute pelvic inflammatory disease

Baseline characteristics

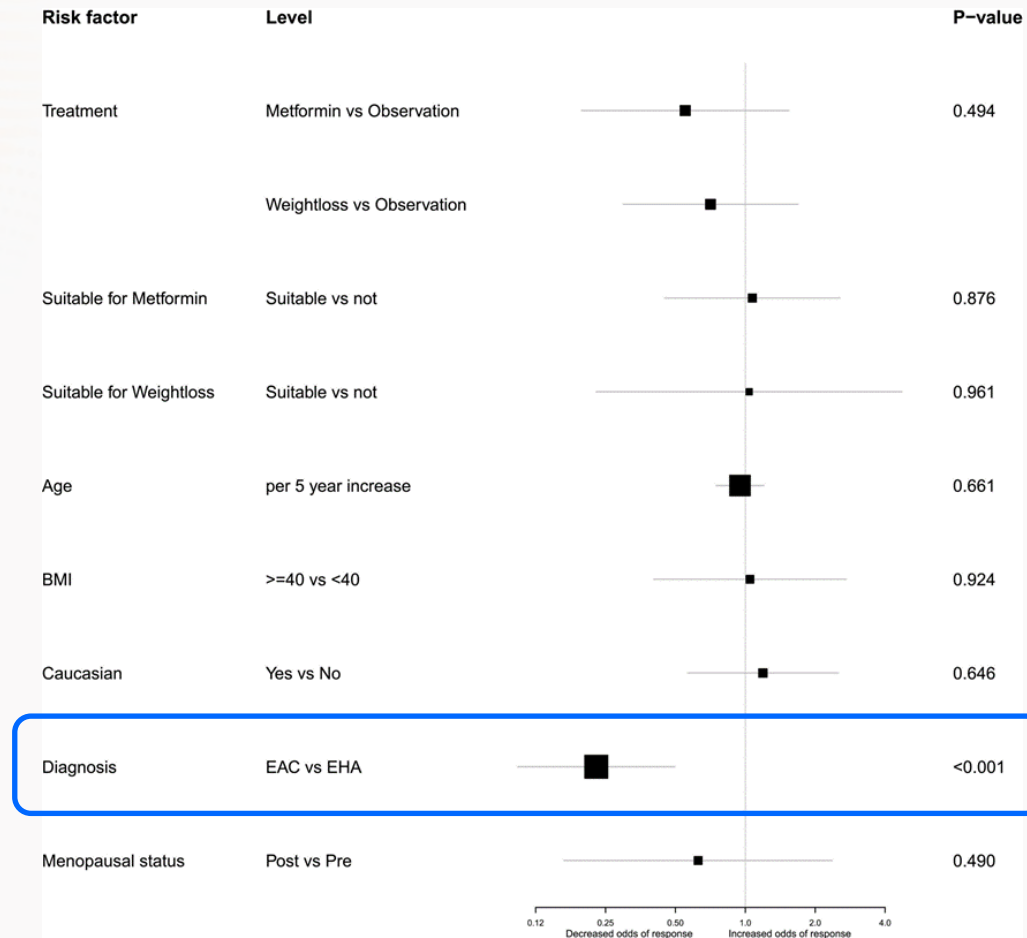
		3-arms	2-arms: LNG-IUD vs LNG-IUD + WL	2-arms: LNG-IUD vs LNG-IUD + M	All participants
# Randomised		91	63	11	165
Diagnosis	EHA	44 (48%)	23 (37%)	2 (18%)	69 (42%)
	EAC	47 (52%)	40 (63%)	9 (82%)	96 (58%)
Menopausal status	Pre	42 (46%)	24 (38%)	5 (45%)	71 (43%)
	Post	49 (54%)	39 (62%)	6 (55%)	94 (57%)
Age (years)	mean, SD	51.5 (14.1)	53.9 (13.4)	60.6 (13.8)	53.0 (13.9)
BMI (kg/m ²)	mean, SD	48.0 (9.7)	48.3 (9.0)	43.1 (9.6)	47.7 (9.4)
Charlson comorbidity index	0	34 (37%)	11 (17%)	2 (18%)	47 (28%)
	≥1	57 (63%)	52 (83%)	9 (82%)	118 (72%)
CA125 (U/mL)	mean, SD	14.5 (5.5) (n=90)	12.7 (4.8) (n=62)	13.7 (6.3) (n=11)	13.8 (5.3) (n=163)

Pathological complete response



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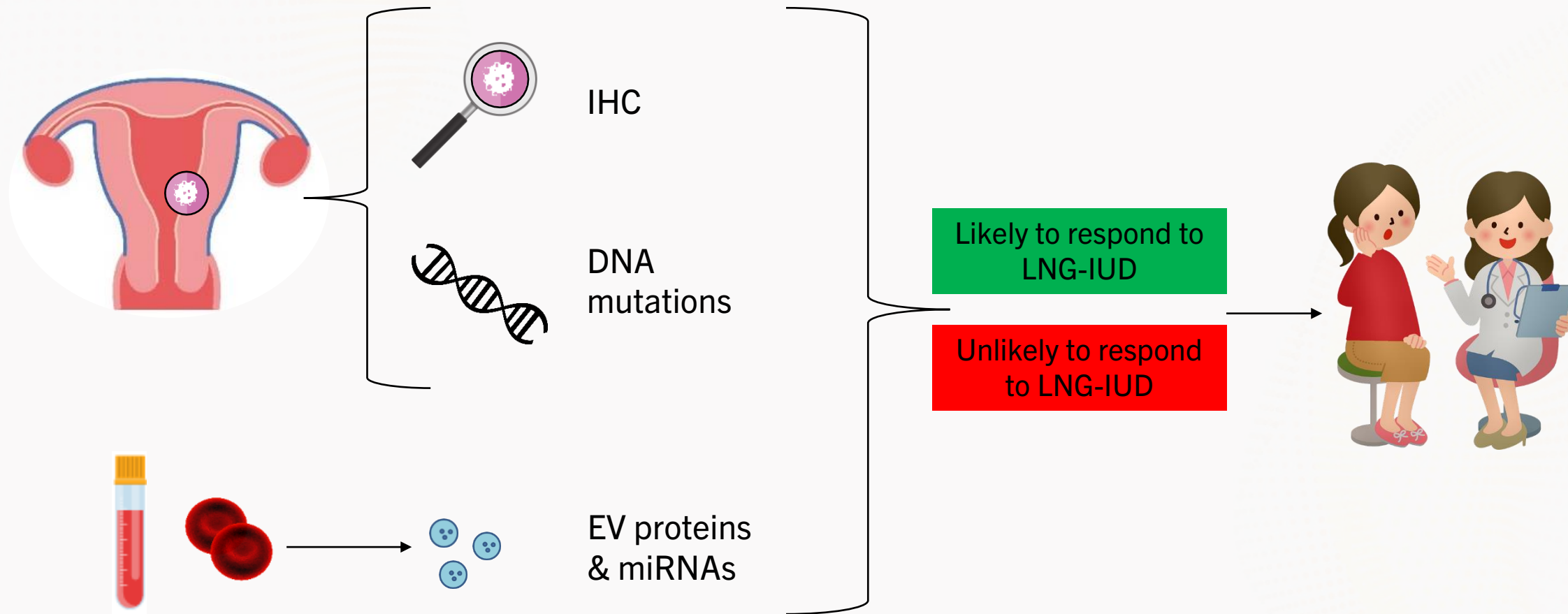
Predictors of response



pCR:
82% EHA
43% EAC

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feMMe molecular project



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Thank you

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