Clinical Trials

Developing successful partnerships

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Overview

- Need for a new study
- Which Research Partner to choose?
- Phases of project – benefits of research partners
- Benefits/pitfalls choosing research partner
- Costs

Claim-driven study design - strategy

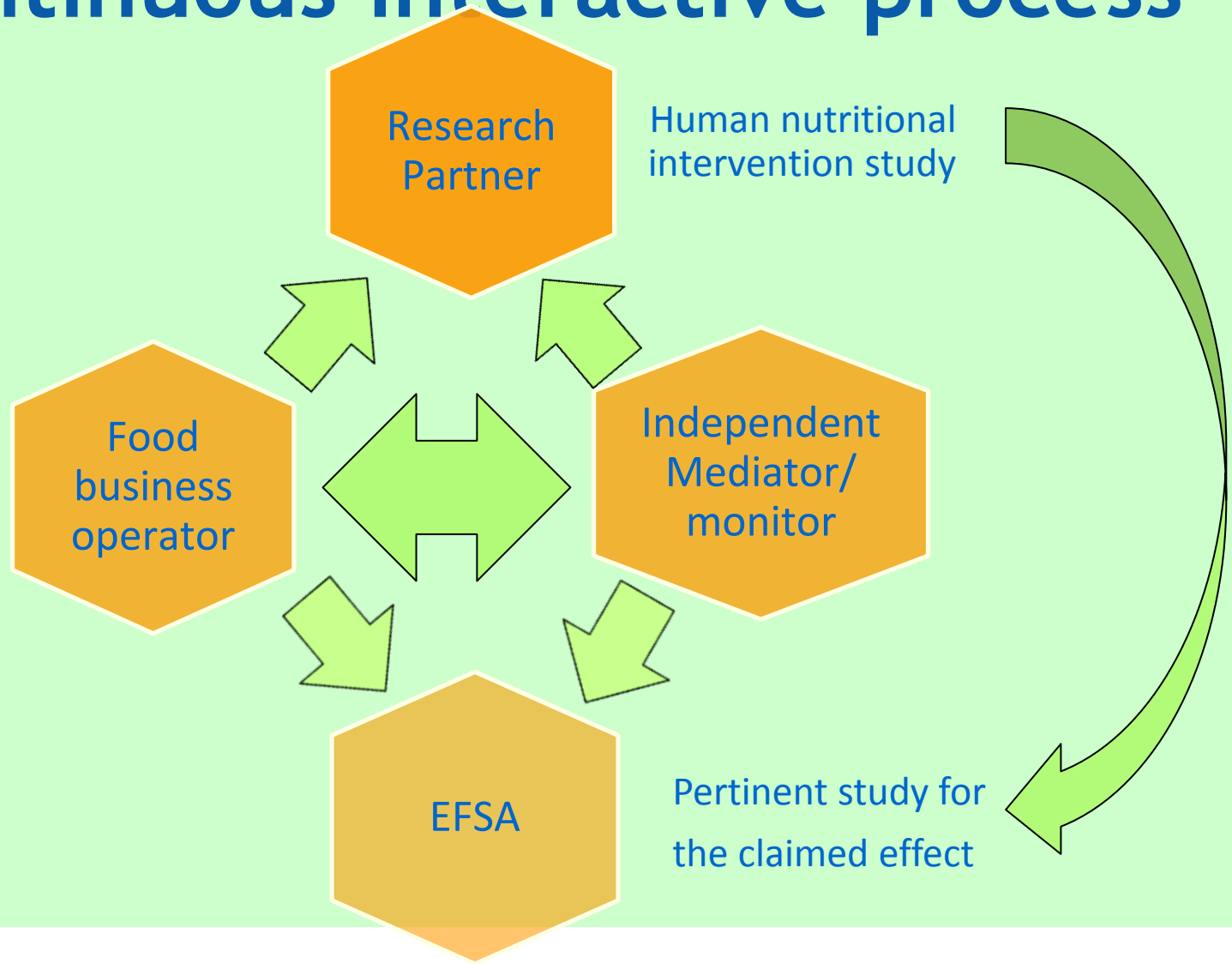
New claim-driven studies required for:

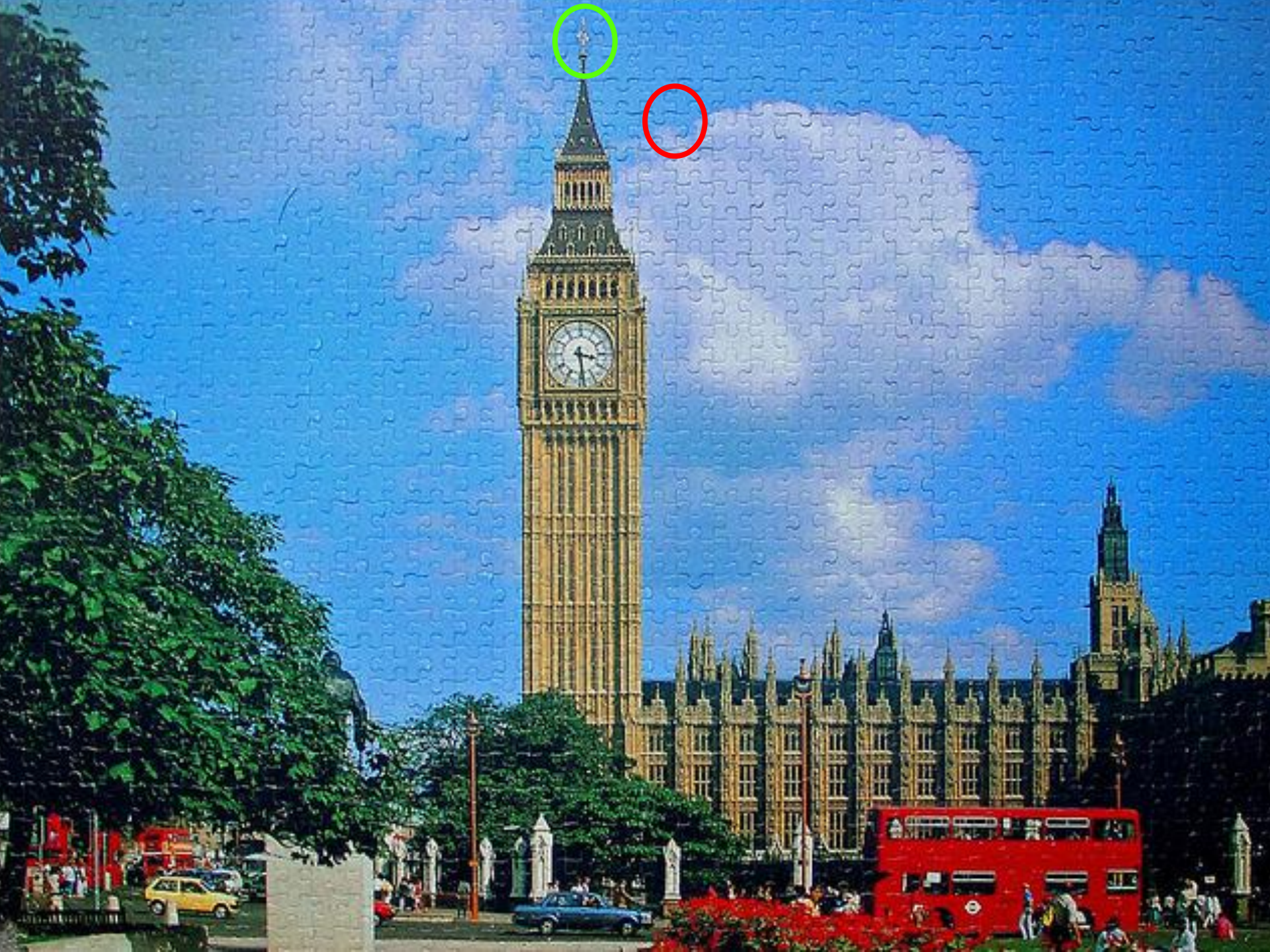
- New ingredient/food
- New ingredient/food – no cause-effect/insufficient evidence
- ‘old’ ingredient/food – new health benefit
- ‘old’ ingredient/food – no cause-effect/insufficient evidence

Which Research Partner?

	University/Academic Hospital	CRO
Clinical study	When within Research Interest	Customised trials
Statistical expertise	Likely?	Likely?
Regulatory expertise	Unlikely	Likely
EFSA mindset	No	Hopefully

Designing and executing trial - Continuous interactive process





Benefits of choosing the right trial partner

1. • Protocol
2. • Contract, IPR and publication rights
3. • Recruitment phase
4. • Execution of the study
5. • Conclusions and discussions

1. Protocol & ethical approval

1. In principle, the protocol should:

- Be based on EFSA requirements & mindset
- Be no different when developed at a university or a CRO
- Ehtical approval procedures should not be different

1.Protocol

- Study design should preferably allow more than basic statistics
- Validated techniques!!
- Established methods!!

1.Ethical approval

However, be aware of the importance of:

- ✓ The rationale of the study
- ✓ Power calculation and sample size determination
- ✓ Randomisation scheme
- ✓ Material and methods section
- ✓ Inclusion and exclusion criteria
- ✓ Time schedule
- ✓ Statistical processing

The applicant of the study has an important verifying role to play.

2. Contractual issues

	University	CRO
Contract	Scope Total cost Time Schedule Protocol in annex	Customised trial Total cost Time Schedule Protocol in annex
IPR	Clausule required on IPR	Study propriety of applicant
Publication	Clausule required on publication rights	Applicant to decide

3. Recruitment phase

	University	CRO
Recruitment	From doctor's practice, and via advertisement Higher likeliness of recruiting students and/or university personnel (target population!) Problems with recruitment: • not enough subjects • long inclusion periods	Own database with potential study participants Often efficient

4. The study in execution

- Typically at a CRO the execution of study is in compliance with quality procedures (however, quality assurance audit often not independent).

- This is not typical for studies performed at Universities – requires more intensive reviewing involvement of applicant!

4. The study in execution

Montoring of data acquistion by Applicant

- Insist on procedure for regular checking of data aquisition during the trial to limit missing data (esp. when study has multiple time points).
- Checking drop-outs – if drop out rate is high, study should not be ended but recruitment continued –
- *underpowered study!! – waste of money!*

4. Statistical analyses of data

Data set:

- Check for normality of the data
- Check for outliers

5. Conclusions and discussions

	University	CRO
Final report	Manuscript	Draft report for approval Final report
Conclusions	Manuscript	Reporting on statistical significance of primary/secondary endpoints
Discussion	Manuscript	During closure meeting

Main benefits

3 Main benefits of choosing a CRO

1. Professional Management of a Customized clinical trial
2. Respecting trial planning (efficient time-keeping)
3. Straighforward reporting of results

3 main benefits of choosing a University

1. Scientific discussion on the results
2. Often leading to recommendations for next trials
3. Publication/participation in conferences

Common pitfalls

- No EFSA-mindset! – HC tailored trial?
- Design (statistical plan) & Power calculation
- Multiple/inappropriate endpoints
- Inappropriately validated techniques/methodologies

Costs vs. return on investment

- EFSA mindset! – be very challenging to not only get a customized trial but also a tailored study

- Focus!


Thank you!


Thank you!


Thank you!
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