

Dos and Don'ts of Creating a Registry

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BAD
DECISIONS
MAKE | GOOD
STORIES





Database

compilation of
information

Registry

functional repository with carefully
designed data storage infrastructure
and processes for data collection

Database

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Registry

functional repository with carefully
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- predetermined set of data for all patients in the repository
- data are collected prospectively
- system that allows for aggregation and querying of composite data
- requires ongoing follow-up data collection
- follow-up data are connected for each individual patient within the registry data infrastructure
- method of quality assessment

Don't:

Plan an enormous undertaking



Do:

Aim higher than this



Hereditary Endocrine Neoplasia Registry

MEN1

MEN2

VHL

NF1

VUS

**Hereditary
PGL
syndromes**

**Hereditary
PHPT
syndromes**

MEN4

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THE UNIVERSITY OF TEXAS

MDAnderson
~~Cancer~~Center

Making Cancer History®

Hereditary Endocrine Neoplasia Registry

MEN2

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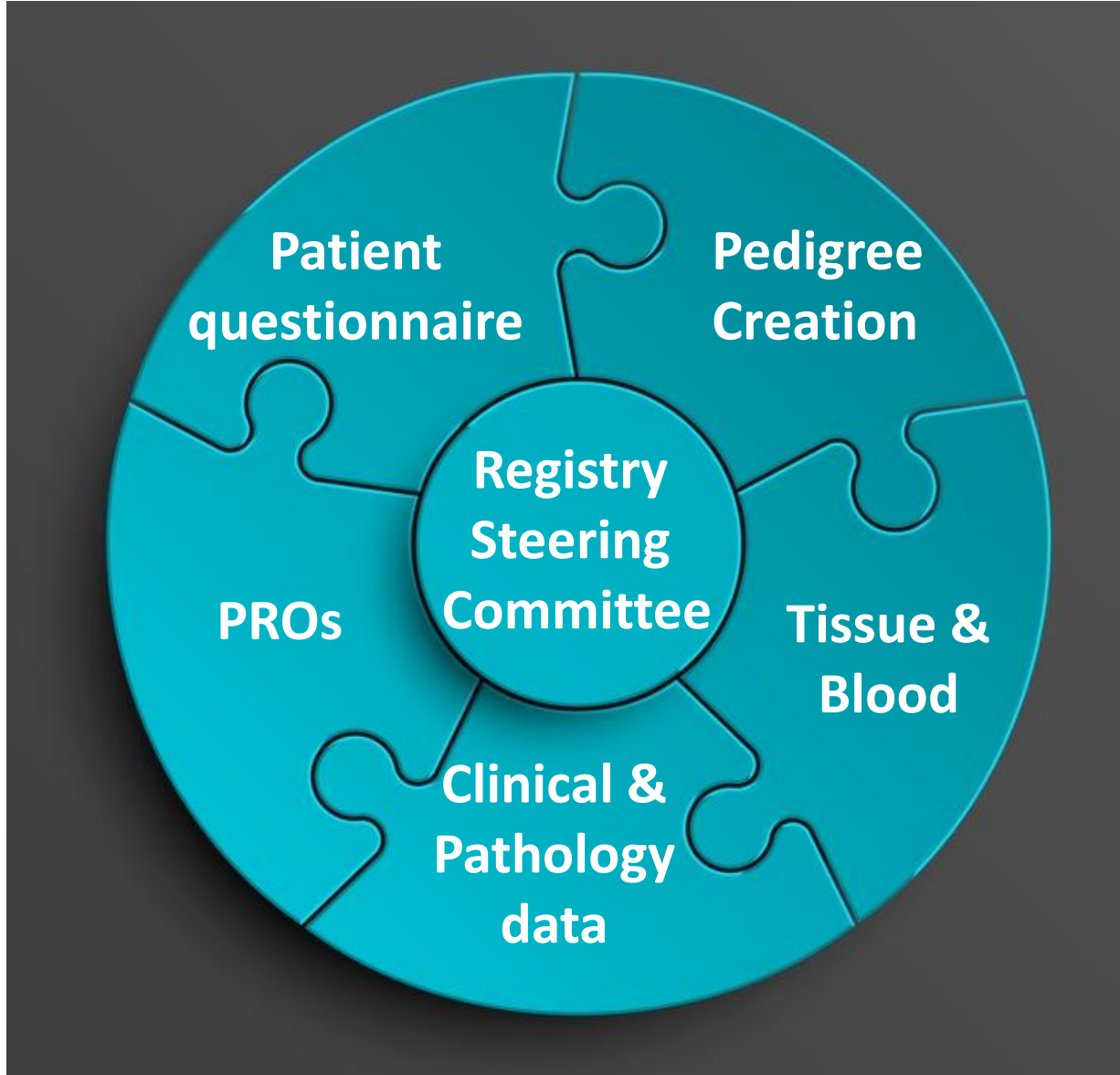
Don't:

Bite off more than you can chew



Hereditary Endocrine Neoplasia Registry

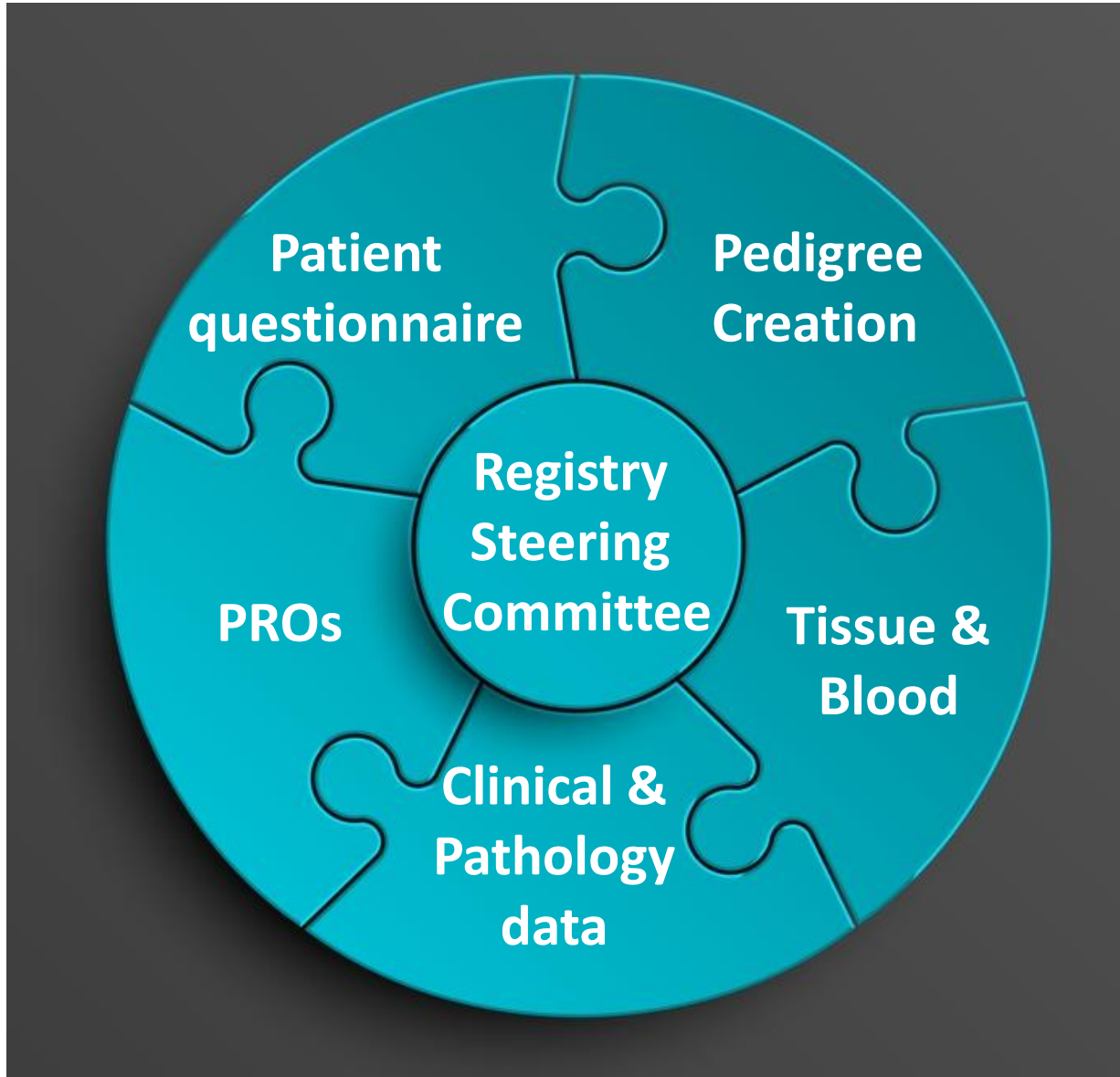
MEN2



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Hereditary Endocrine Neoplasia Registry

MEN2



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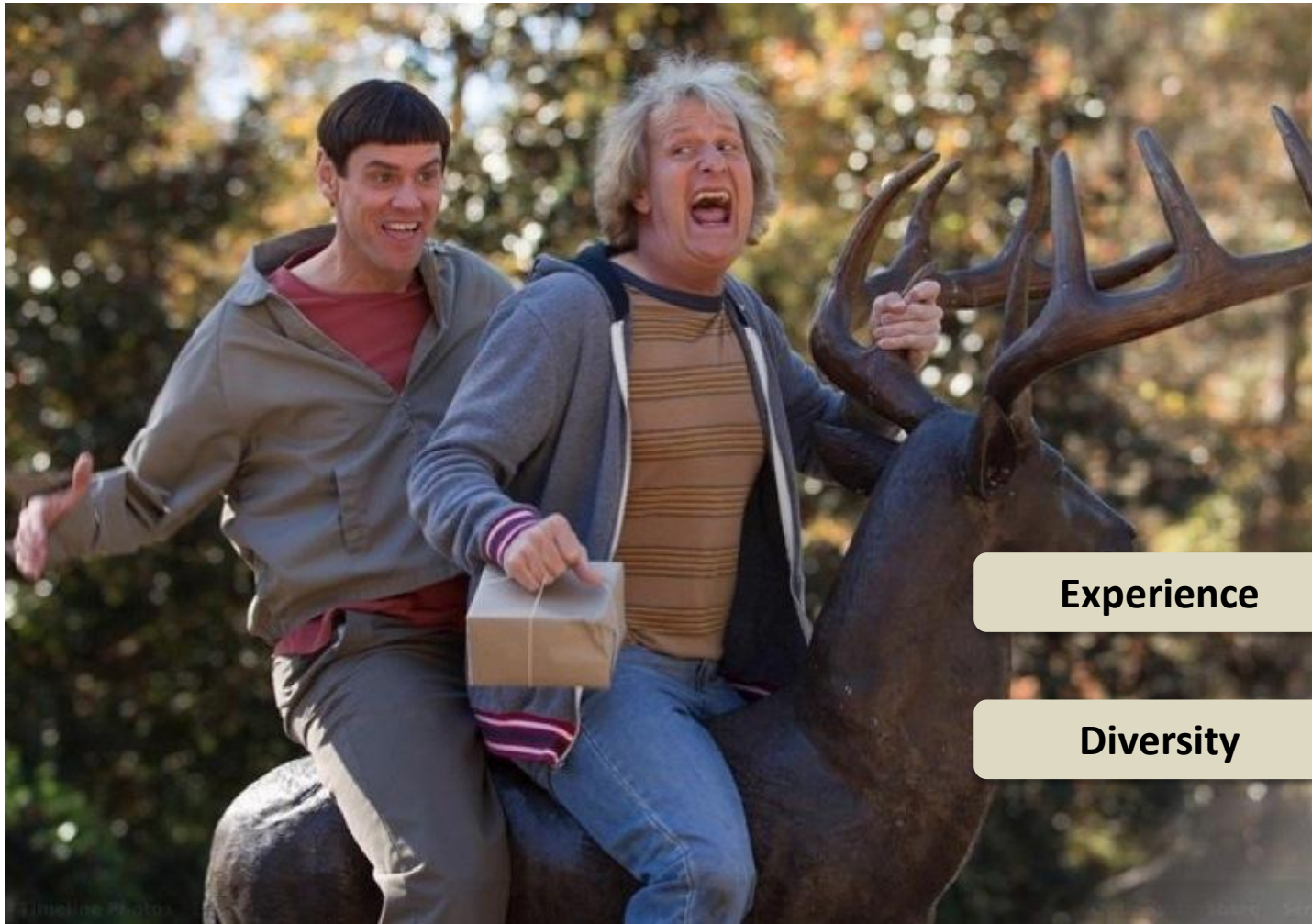
Do:

Pick your collaborators wisely



Do:

Pick your collaborators wisely

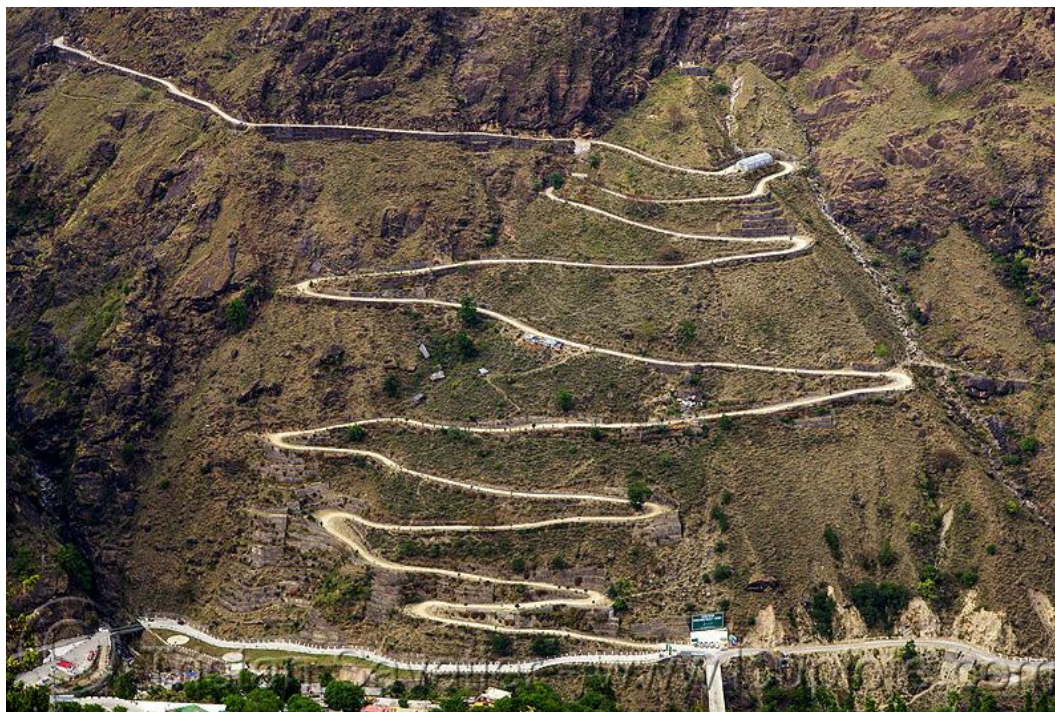


Experience

Diversity

Do:

Plan reasonable phases



Phases of the registry

Phase 1 – Enroll patients at my institution

- Retrospectively complete
- Prospectively active

Phase 2 – Enroll patients nationally and internationally

- Strategic partnership with AMEND & ThyCa
- Prospectively active

Phase 3- Partner with other academic institutions

- Utilize Progeny Platform and REDCap
- Contract made with first institution

Don't:

Think of the IRB as an afterthought

Initial IRB Appendices

Appendix	Title
Appendix A	Hereditary Cancer Syndromes with Endocrine Neoplasia overview
Appendix B	Consent form for adult participants
Appendix C	Consent form for minor participants
Appendix D	A sample letter given to patients in clinic to help inform family members of the diagnosis of a hereditary cancer syndrome
Appendix E	Registry information letter for family members
Appendix F	Cover letter sent with the medical and family history questionnaires to participants recruited through the mail
Appendix G	Demographic and medical history questionnaire used with patients seen in the CGC
Appendix H	Study Questionnaire
Appendix I	Saliva collection kit
Appendix J	Retrospective recruitment letter
Appendix K	General Study Information Sheet (also for Internet)
Appendix L	Medical Release Form
Appendix M	Variables to be collected in registry database (data dictionary)
Appendix N	Telephone Recruitment of Participants to GENR
Appendix O	Telephone interview tool
Appendix P	Family contact form
Appendix Q	Annual recontact form
Appendix R	Longitudinal tracking form
Appendix S	Study advertisement
Appendix T	Quality assurance overview/schema

Do:

Pick something you are passionate about





Questions?





Effective Health Care Program

Volume 1

**Registries for
Evaluating Patient
Outcomes:
A User's Guide**



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