# PCCM Fellowship: Research Track Overview

Henry Ford Hospital

**Scholarly Activity**

Both tracks
- Journal clubs
- Present clinical talks

Research Track

Clinical Track

Research electives
- Original Research project
- Secondary projects
- Present findings nationally (ATS, CCM, Chest)
- Manuscript
- Publish

Clinical electives
- QI Project still required
- Clinic during electives maintained
- May still do case report
- May still attend national conferences

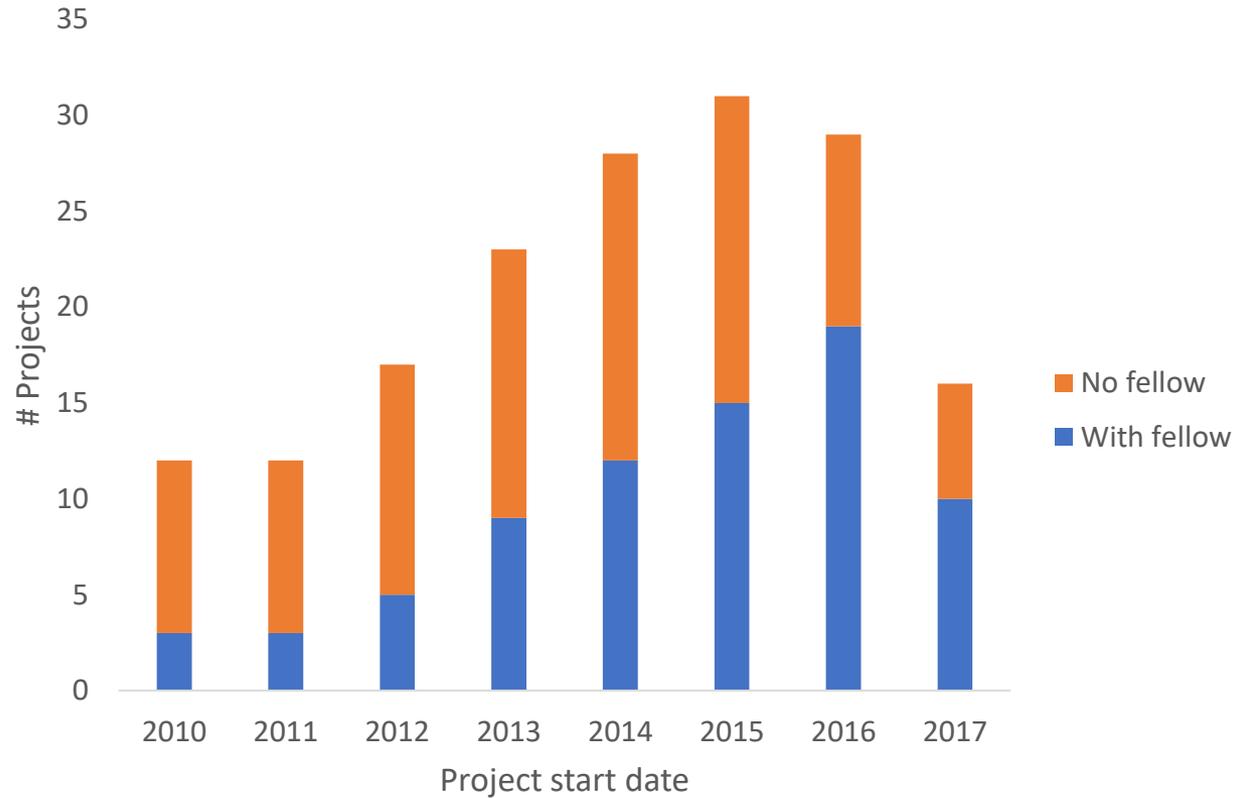# Log in to look at pool of ongoing projects

- Help to pick a PI by looking at staff research
- Help to pick an ongoing (but abandoned) project as your secondary project
- Log in to look at your own progress.

# SPARQ:
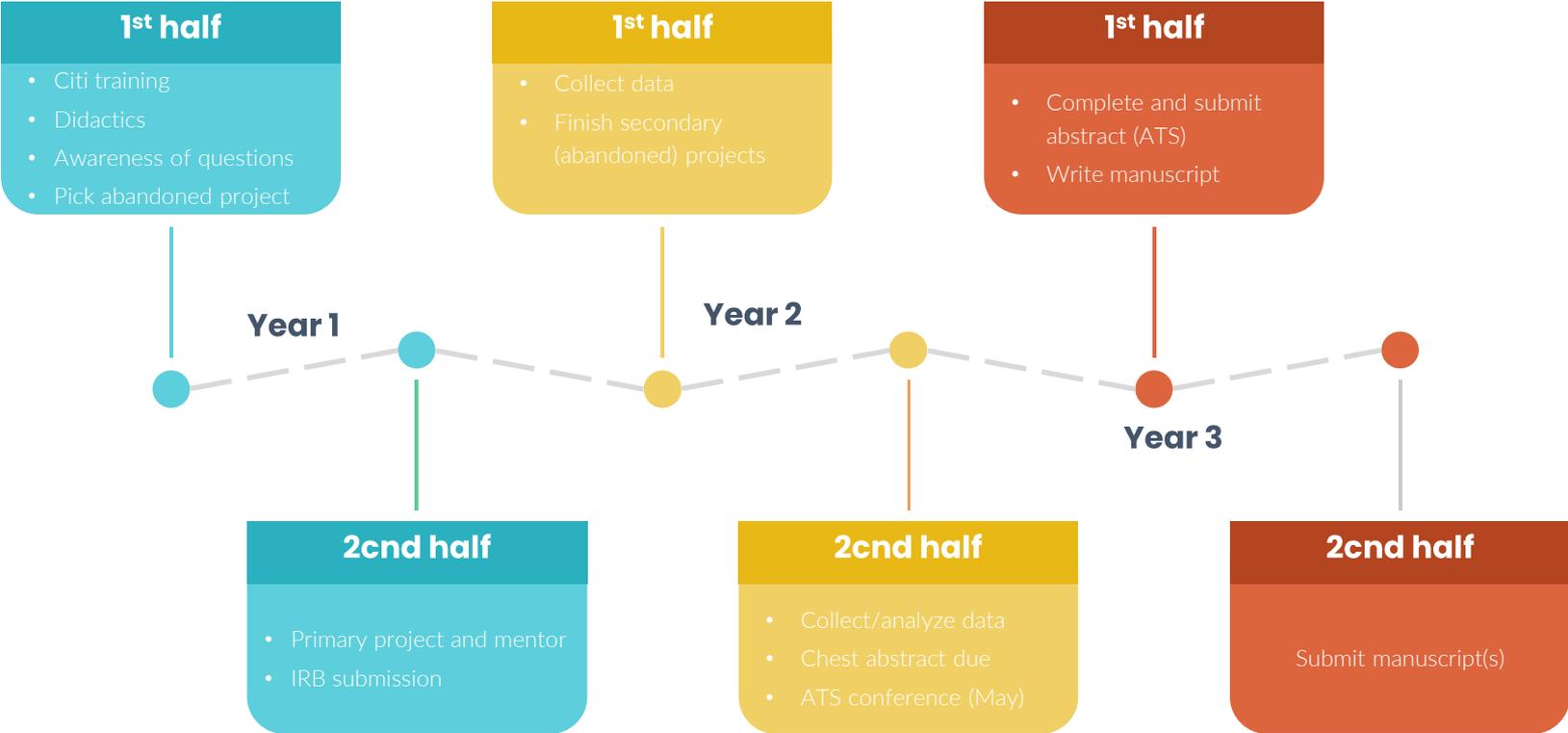## Systematic Process to Advance Research and QI projects

- Started Spring 2013
- Goal: facilitate success in research projects
  - Fellow research experience
  - Exposure to research
    - Developing ideas, study design, scientific method
  - National presentations
  - Original research vs case reports
  - Publication rates
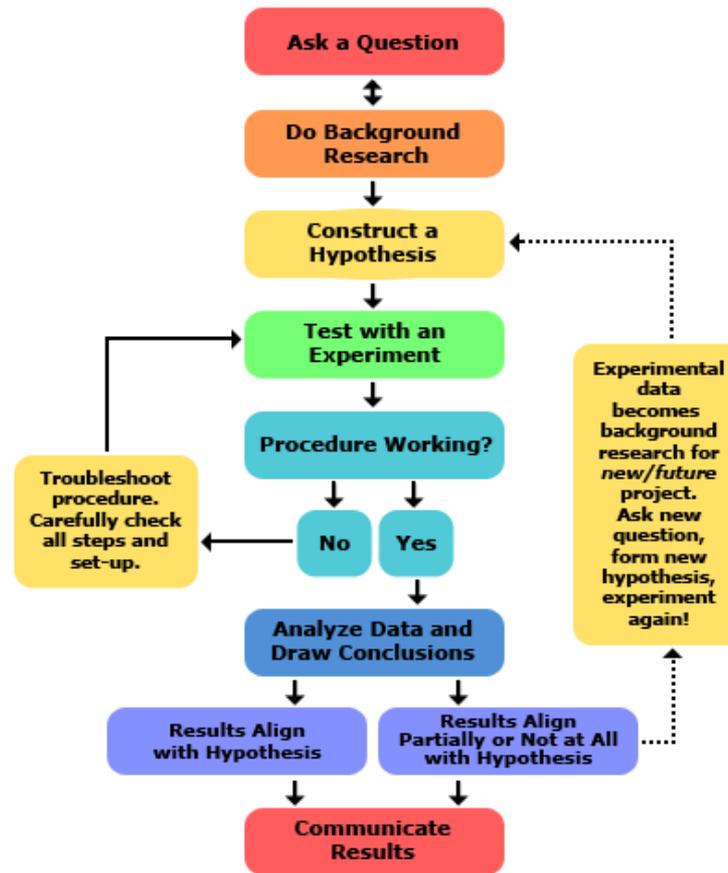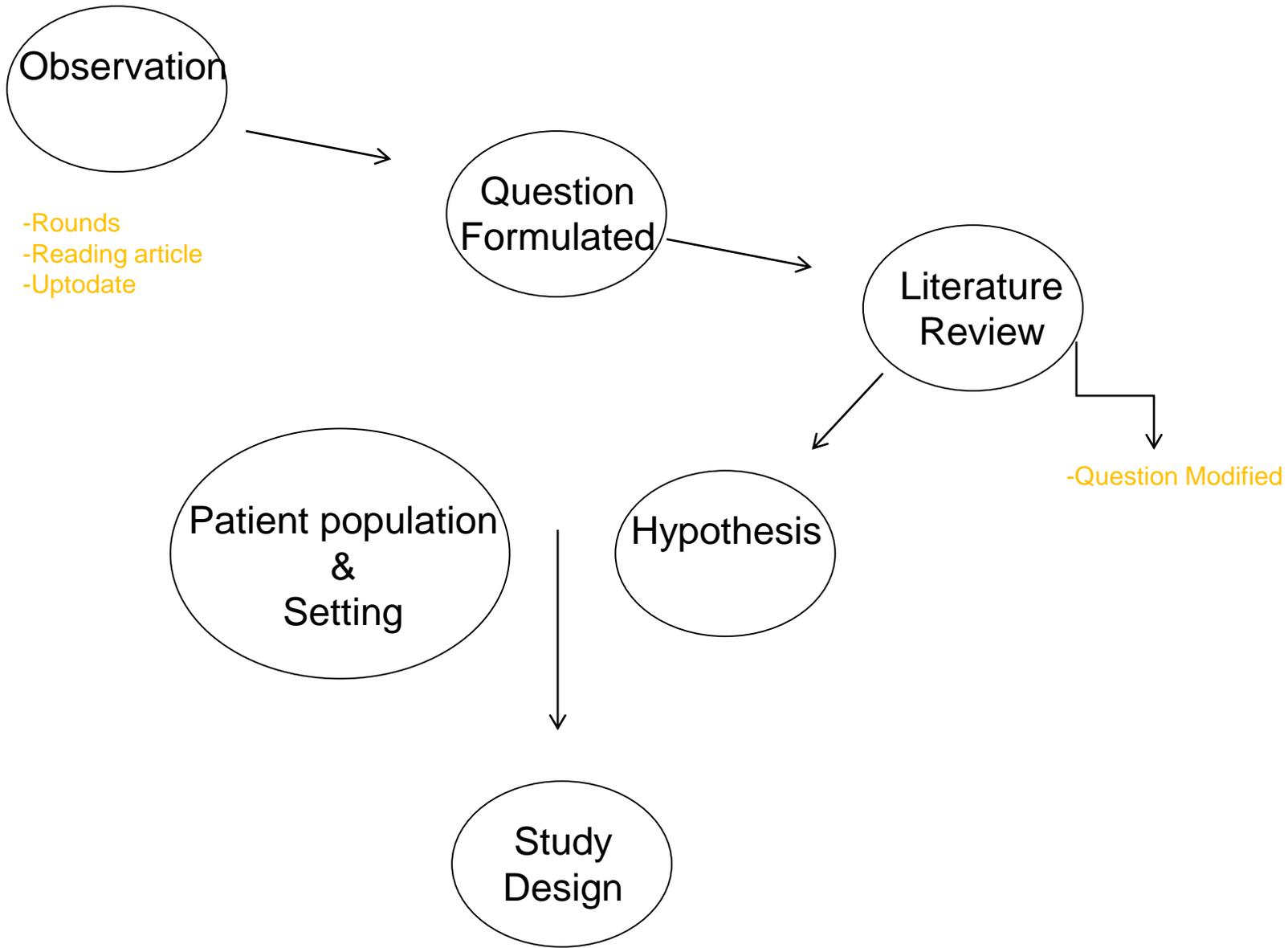
# % original research with fellows

# TIMELINE

Research roadmap

## Year 1

**1st half**
- Citi training
- Didactics
- Awareness of questions
- Pick abandoned project

**2cnd half**
- Primary project and mentor
- IRB submission

## Year 2

**1st half**
- Collect data
- Finish secondary (abandoned) projects

**2cnd half**
- Collect/analyze data
- Chest abstract due
- ATS conference (May)

## Year 3

**1st half**
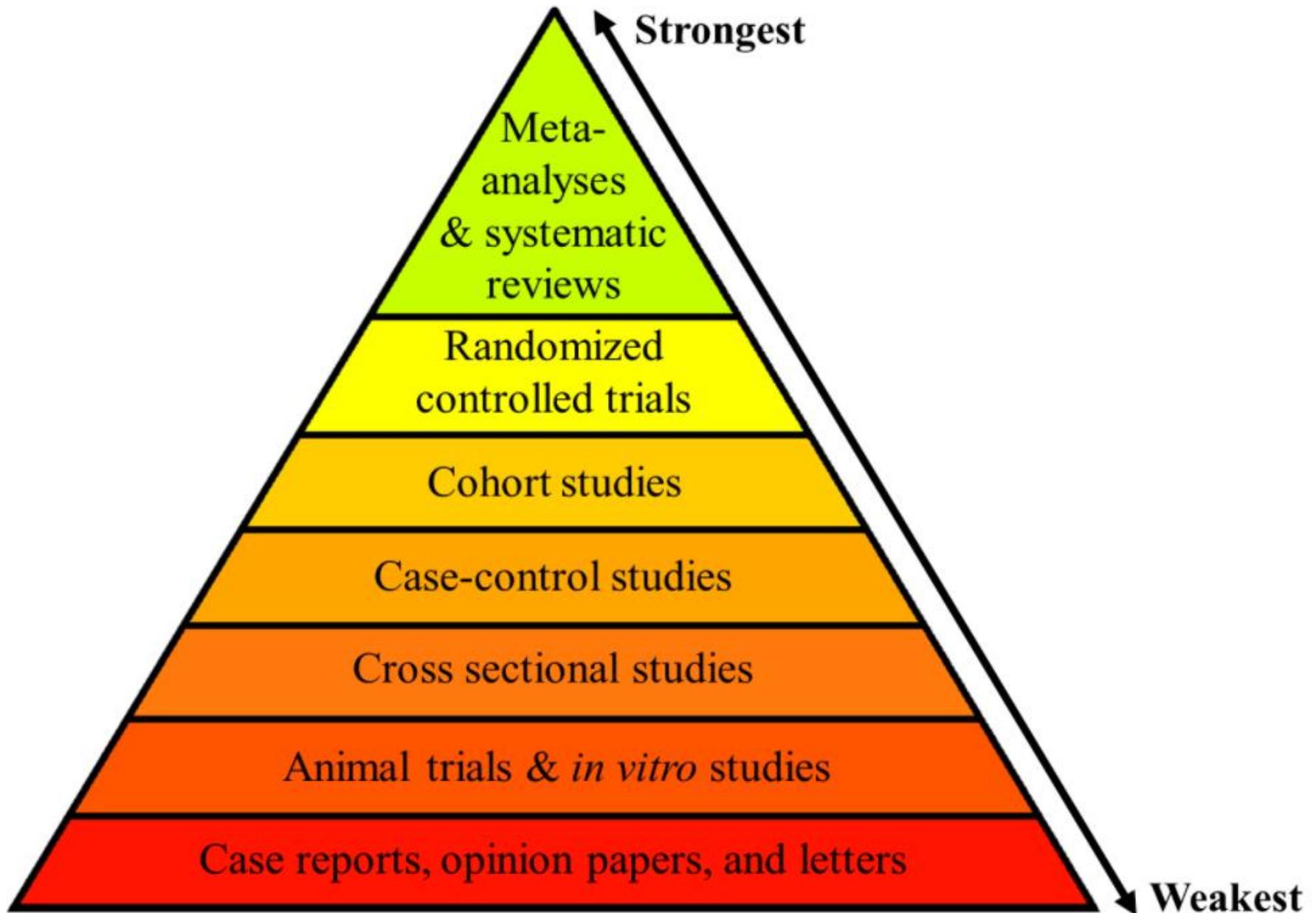- Complete and submit abstract (ATS)
- Write manuscript

**2cnd half**
- Submit manuscript(s)

# Scientific Method

a way to ask and answer scientific questions by making observations and doing experiments

Observation

-Rounds
-Reading article
-Uptodate

Question Formulated

Literature Review

-Question Modified

Patient population & Setting

Hypothesis

Study Design

# Hierarchy of Scientific Evidence

Hierarchy of Scientific Evidence

Strongest
- Meta-analyses & systematic reviews
- Randomized controlled trials
- Cohort studies
- Case-control studies
- Cross sectional studies
- Animal trials & *in vitro* studies
- Case reports, opinion papers, and letters
Weakest
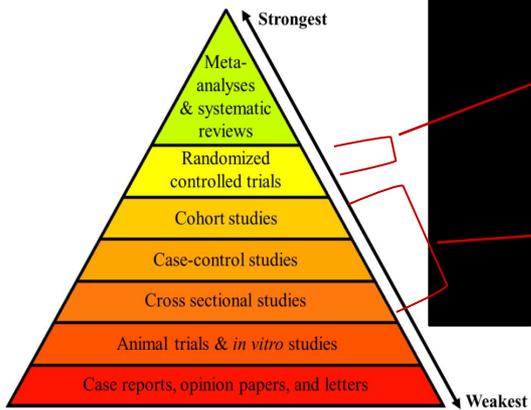
| | How to study: | examples |
|---|---|---|
| Interventional | **Intervene** in one group and measure the difference | Randomized controlled trial |
| Observational | **observing** natural relationships between factors and outcomes | Cross-sectional, Case Control, Cohort |

# Cross-sectional studies

- In a population of patients:
  - prevalence of disease and/or exposure at one moment in time

| | Present CHD | | Absent CHD | | Total |
|---|---|---|---|---|---|
| Not active | 50 | a | b | 200 | 250 |
| Active | 50 | c | d | 700 | 750 |
| Total | 100 | | | 900 | 1000 |

$P_1$= a/a+b= 50/250 = 20.0% prevalence of CHD among people who are not active.

$P_0$= c/c+d = 50/750 = 6.7% prevalence of CHD among people who are active.

- Takes place at a single point in time

- Does not involve manipulating variables

- Look at numerous characteristics at once (age, income, gender, etc.)

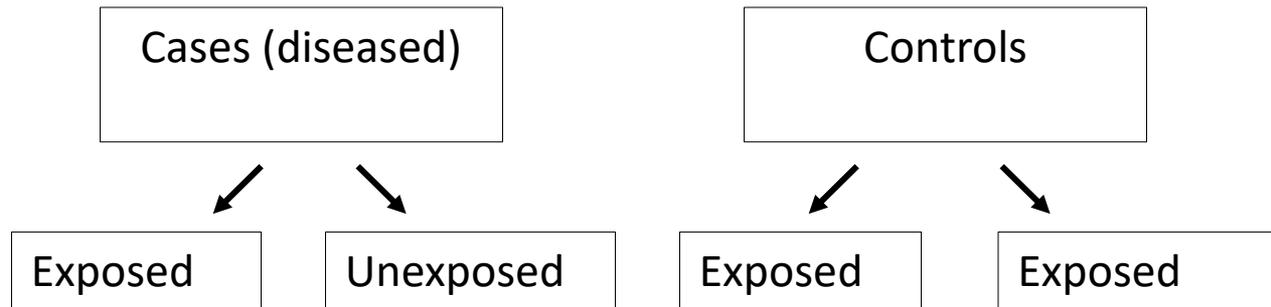- It's often used to look at the prevailing characteristics in a given population

# Cross-sectional studies

<u>Limitations</u>

- Not causal or relational
- Can't determine the cause of an outcome
- Only used for prevalence
- Hypothesis generating if there is a difference between the groups

- Takes place at a single point in time
- Does not involve manipulating variables
- Look at numerous characteristics at once (age, income, gender, etc.)
- It's often used to look at the prevailing characteristics in a given population

# Case-control studies

participants selected based on the outcome status

| Cases (diseased) | | Controls | |
|---|---|---|---|

| Exposed | Unexposed | Exposed | Exposed |
|---|---|---|---|

|  | Cases | Controls | Total |
|---|---|---|---|
| Exposed | a | b | a+b |
| Unexposed | c | d | c+d |
|  | a+c | a+d | a+b+c+d |

$$OR = \frac{a/c}{b/d} = \frac{ad}{bc}$$

# Case-control studies

- Strengths
  - Cost effective
  - Retrospective: can study diseases with long latency periods.
  - Efficient for the study of rare diseases.
- Weaknesses
  - Prone to bias;
    - selection, recall and observer bias.
  - Limited to examining one outcome.
  - Can't estimate incidence rates
  - Poor choice for the study of rare exposures.
  - The temporal sequence between exposure and disease may be difficult to determine.

# Cohort study

participants selected based on the exposure status

Risk factor

Exposed    Unexposed

Followed over time
(retrospective or prospective)

Disease?
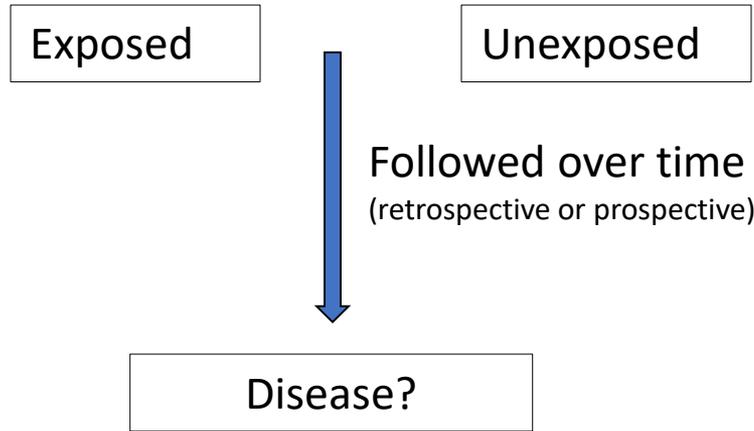
| | Lung cancer | No lung cancer | Total | Incidence rate |
|---|---|---|---|---|
| Smoker | 42 | 27,000 | 27,042 | 1.5/1000/yr |
| Non-smoker | 7 | 63,000 | 63,007 | 0.1/1000/yr |
| Total | 49 | 90,000 | 90,049 | |

RR = 1.5/0.1=15

"The risk of cancer is 15x higher in smokers"

# Cohort studies

- Strengths
  - Multiple outcomes & exposures can be measured
  - Exposure AC disease: causality can be determined
  - Incidence and prevalence can be measured.

- Weaknesses
  - Prone to bias- loss to follow-up, confounding, exposure status
  - Participants may move between one exposure category.
  - Poor choice for the study of a rare disease.
  - Classification of individuals (exposure or outcome status) can be affected by changes in diagnostic procedures.
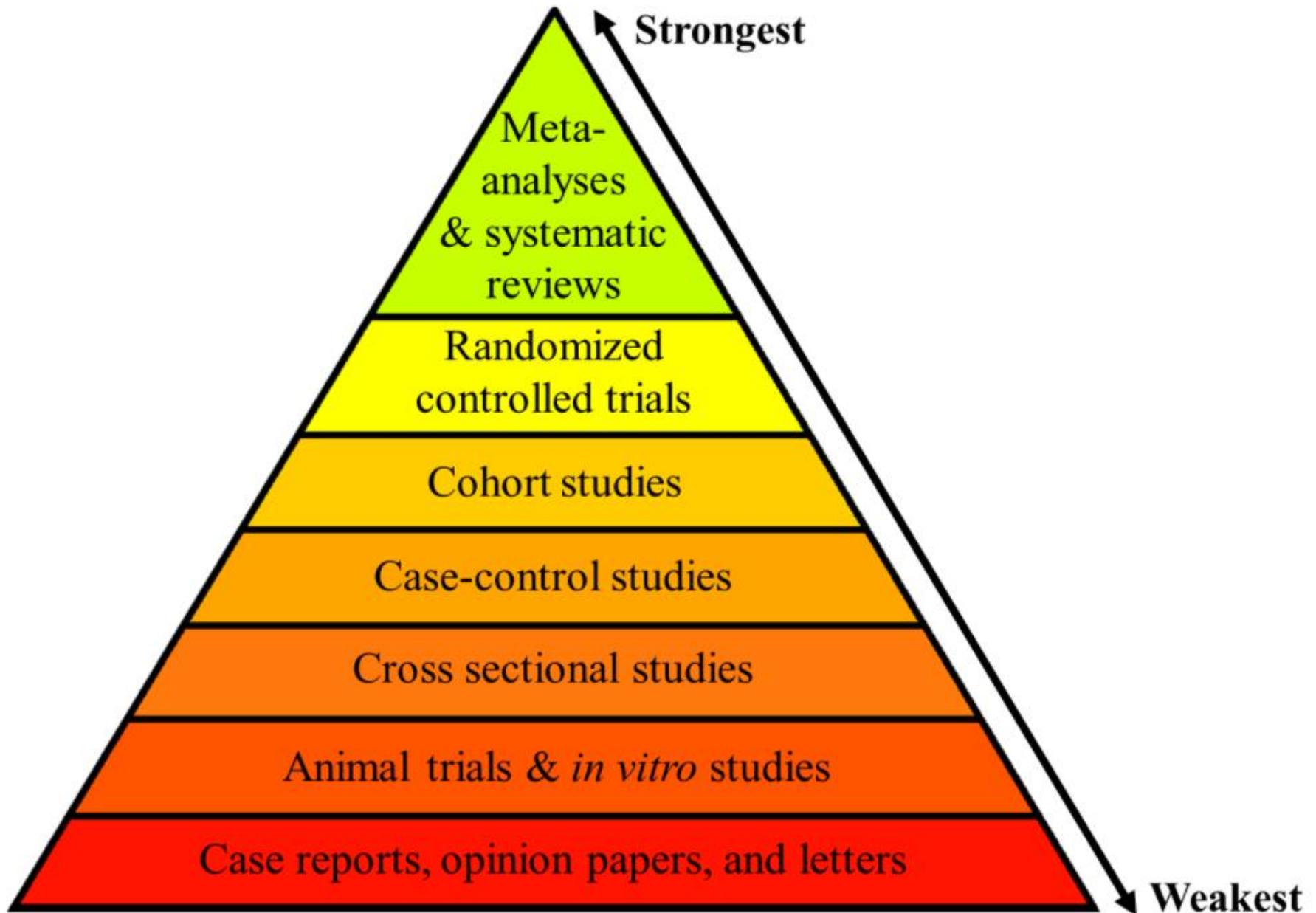
# CC and Cohort
# (types of observational studies)

|  | Case Control | Cohort |
| --- | --- | --- |
| Test association between exposure and outcome | Yes | Yes |
| Odds Ratio | Yes | Yes |
| Rate of outcome | No | Yes |
| Sample size | Smaller (depend on prevalence of outcome) | Bigger (depend on rate of outcome) |

Why sample size Req. different?

rate of outcome is usually smaller than the prevalence of the exposure

# Hierarchy of Scientific Evidence



Strongest

Meta-analyses & systematic reviews

Randomized controlled trials

Cohort studies

Case-control studies

Cross sectional studies

Animal trials & *in vitro* studies

Case reports, opinion papers, and letters

Weakest

# Randomized controlled (RCT)

- Randomization is the strength
  - Controls for unmeasured "confounders" by distributing randomly between groups
  - Prospective
  - Time consuming. Need lots of resources
  - Usually not feasible without a dedicated screener (even if the n is do-able)
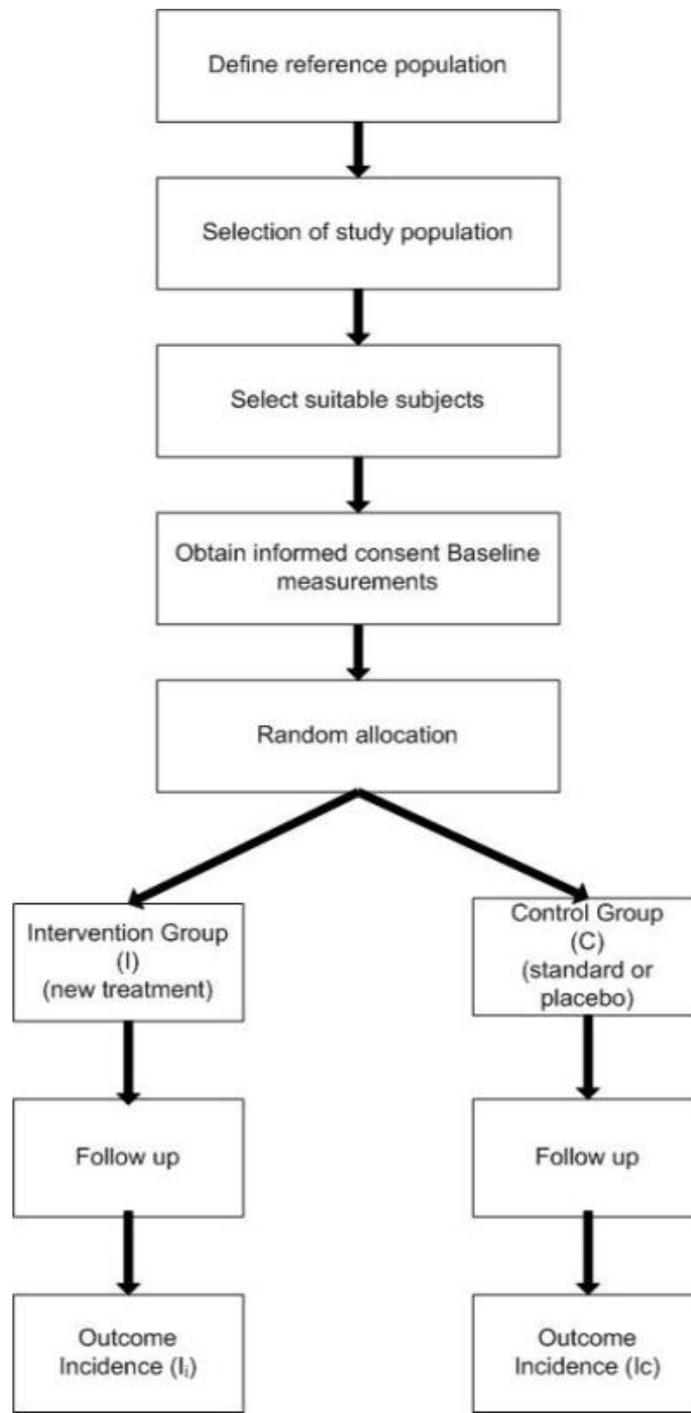
# Case reports/series

- Report
  - Collections of reports on the treatment of individual patients, or
  - Single patient
- little statistical validity
  - No control group to compare outcome/disease
  - Conclusions to extrapolate is limited

# Case reports should show one of the following:

- Unreported or unusual side effects or adverse interactions involving medications
- Unexpected or unusual presentations of a disease
- New associations or variations in disease processes
- Presentations, diagnoses and/or management of new and emerging diseases
- An unexpected association between diseases or symptoms
- An unexpected event in the course of observing or treating a patient
- Findings that shed new light on the possible pathogenesis of a disease or an adverse effect
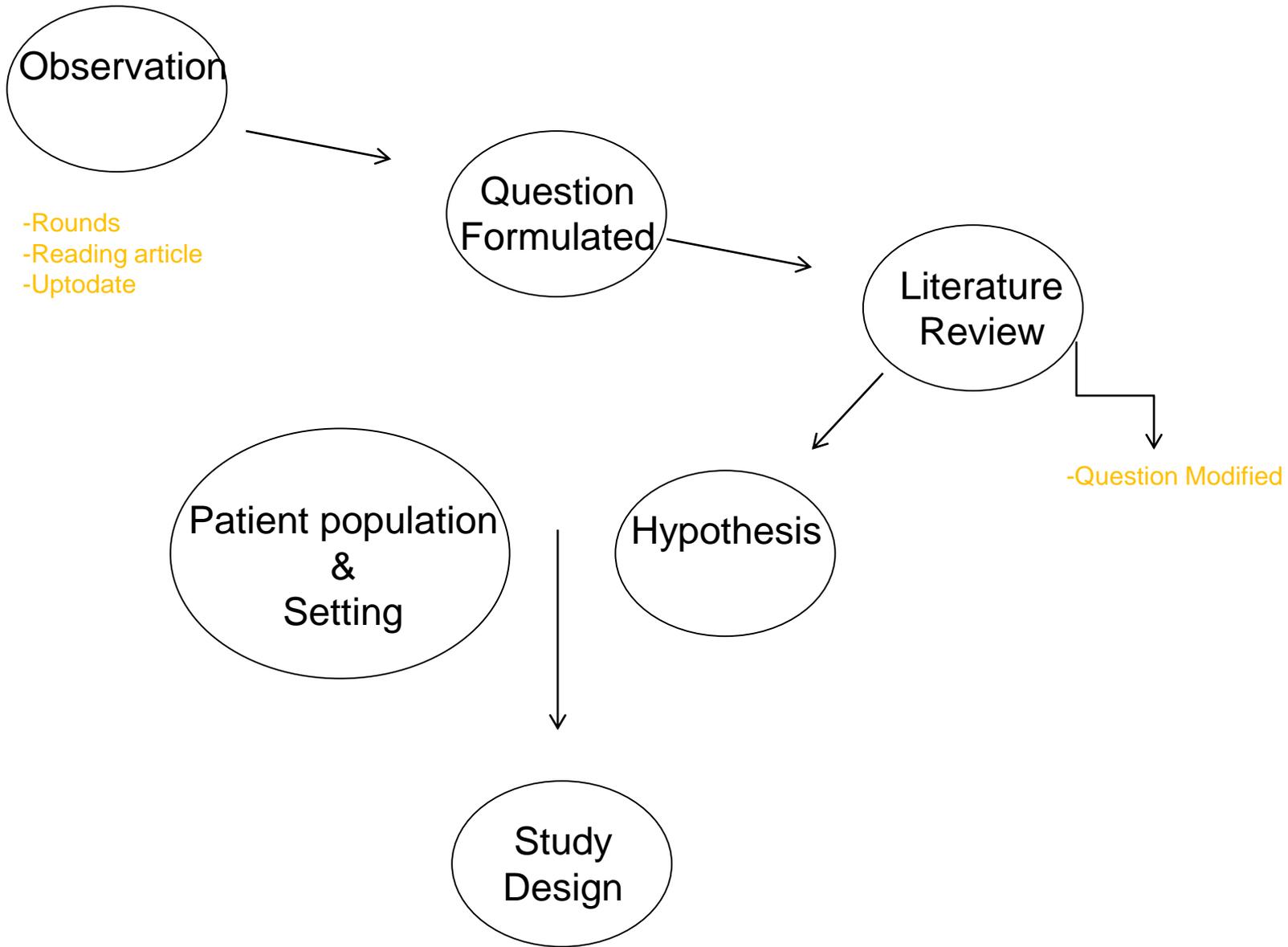
# Case reports

**Advantages**

- Useful message

- Awareness of a rare problem

- Limited resources needed

- Increases #pubs on your CV

**Disadvantages**

- Rarely drives the field forward

- Does not teach you about the scientific method

- Case reports on CVs are usually ignored (especially if never published)

Observation

-Rounds
-Reading article
-Uptodate

Question Formulated

Literature Review

-Question Modified

Patient population
&
Setting

Hypothesis

Study Design

# Research skills

- Effective literature searches
- Developing a Research Question
  - Hypothesis
  - Study design – patient selection, setting
  - Variables, and Outcome Measures
  - Power analysis and sample size calculations
- After data collected
  - Statistical tests (t-tests, regression analysis)
- One journal club that month as schedule permits
- WIPS

# Research Elective – 1$^{st}$ month as 1$^{st}$ year

- Brief reading (Uptodate, articles in JAMA, Chest, NEJM, etc.jj)
  - Devise a research question
- Literature review
- Hypothesis
- Write an introduction (~2 pages)

# Steps to conducting a lit review

1. **Search** for relevant literature

2. **Evaluate** sources

3. **Identify** themes, debates and gaps

4. **Outline** the structure

5. **Write** your literature review

# What is a literature review?

- survey of scholarly sources on a specific topic

- A road that leads to your research question (Introduction)

-  provides an overview of current knowledge

- Identifies
  - Gaps in knowledge
  - Relevant theories on the topic
  - Methods used to study the topic

- Reconciles your results with existing literature (Discussion)

# The literature review process

# Activities not limited to elective month

| | | |
|---|---|---|
| Participate in and complete a research project | idea and hypothesis generation with lit review to vet the idea | Feasibility review |
| IRB submission | Planning and logistics of the project | Periodic WIPS presentations on the project |
| Data collection, analysis | -Abstract for national conference | -Manuscript writing and submission to a peer-reviewed journal |