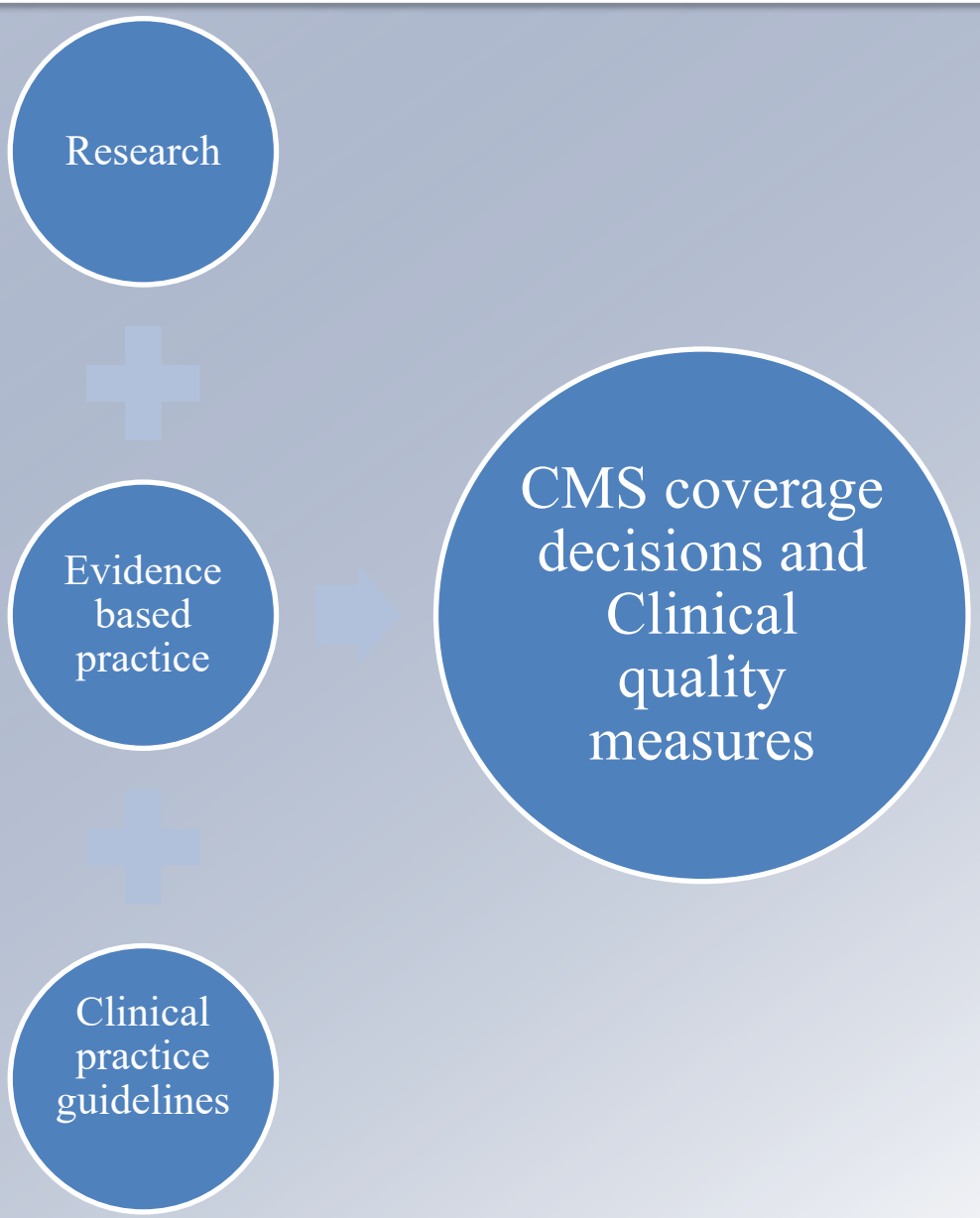
Establishing CMS reimbursement in practice - a process based on evolving ***research***

- Evidence Based Practice (EBP) - the integration of best ***research*** evidence with clinical expertise and patient values
- Clinical Practice Guidelines (CPG's) - developed by multi-disciplinary subcommittees using an evidence-based approach, combining the best ***research*** available with expert consensus on best practice.



What is a Routine costs in ~~clinical trial~~ ***research*** ?

- Items of services that are typically provided absent a clinical trial (e.g., conventional care)
  i. Clinical practice guidelines (i.e. CDC, NIH, NCCN, American Heart Association, American Academy of family Physician, NCBI, etc.)
  ii. Widely accepted and used by most healthcare professionals

- Items or services in excess of Conventional Care and/or Clinical practice guidelines
  i. Clinically appropriate monitoring of the investigational item or service.
  ii. Prevention of complications

- Items or services required solely for the provision of the investigational item or service
  i. Investigational item administration - IV fluids, infusion, injection, IR guidance, Implant and/or surgery etc.

Schedule of Events

- Time points – When is research interacting with the subject, how long and at what frequency (e.g., # of visits, weeks, months, etc.)
- Procedures – What is being done at the time point of interaction for research (consent, medical record review, specimen collection, exam, QOL, etc.)
- Location – Where is the procedure being performed? (**UA space** [red cap, CATS, A2DRC, Prevention clinic, Private UA lab, etc.] or in **Banner clinic space** [any Banner facility to include Sonora quest lab services, and data collection from the Banner EMR])

PI Last name, First Name

PROCEDURES - What procedures, items or services will you have the patient /subject complete / conduct at each time point ?	Time points of patient / subject interaction - When is research interacting with subject and for how long / @ what frequency (e.g., Visit 1, Visit 2, Visit 3, etc.)										Location (Banner or U/A) - Where will services be Performed and/or whose resources are being used ?
	Baseline	Visit 1 - Screening	Visit 2	Visit 3	Visit 4	Visit 5	Follow up Visit 1	Follow up Visit 2	Long Term Follow up	End of study	
	done at screening visit	Day 1	Week 4	Week 8	Week 12	Week 16	Month 6	Month 12	Every year for 3 years		
Informed Consent											UA
Eligibility review											Banner Medical record
Demographic collection											UA - Red Cap
Medical record review											Banner Medical record
Biospecimen collection - Non blood (stool, urine, Nasal Swabs, etc)											UA
Vital Signs											UA
Physical Exam											UA
Adverse Events											UA
Prior Concomitnant Medication / Procedure											UA
Lab work (please specify type of labs to be conducted , CBC, CMP, Amlyase, Lipase, etc.)											UA
Qol's											UA
PRO's											UA
Surgery Data collection											Banner Medical record
Administer study therapy											UA
Imaging											Banner clinic