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FCA Litigation: Leveraging Statistical Sampling and Extrapolation to Prove or Disprove Liability

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Today's faculty features:

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False Claims Act Litigation

July 2021

Leveraging Statistical Sampling to Prove or Disprove Liability

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Introduction

- Panelist introductions:
  - Michael Sullivan, Finch McCranie
  - Chris Haney, Forensus Group
  - Adam Tarosky, Nixon Peabody
- Provide government, relator, defendant, and statistician/expert witness perspectives on the issue.
- Avoid lecturing; use discussion format to explore current and unresolved questions about sampling and extrapolation in FCA cases.

Discussion Topics

Part I Overview of the False Claims Act

Part II What is statistical sampling?

Part III Historical role of sampling in FCA context

Part IV Arguments for and against sampling to prove liability

Part V Considerations for developing and scrutinizing sampling

Part VI Discussion of sampling for various issues of liability

Part VII Recent issues involving sampling in FCA cases

Part VIII Questions

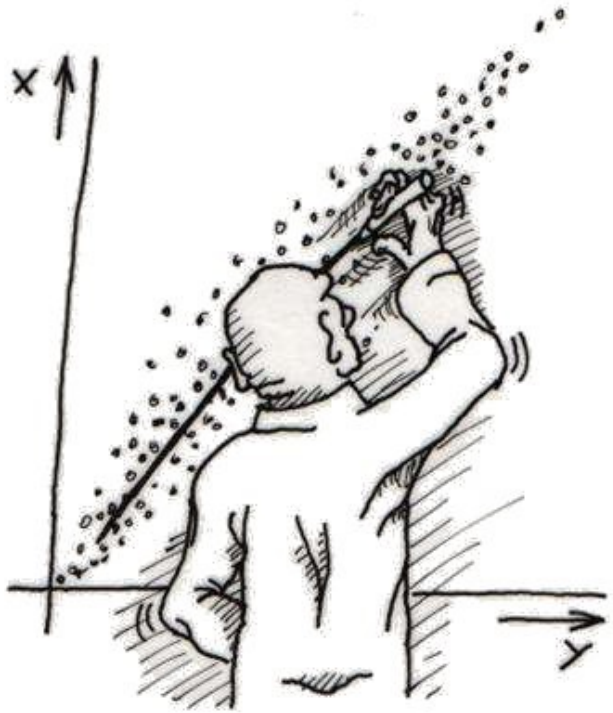
Part IX Appendix

Overview of the False Claims Act

- Government's primary tool for recovering federal funds paid out due to fraud.
- Authorizes private plaintiffs ("relators") to sue on behalf of the government.
- Allows the government to recover treble damages and civil penalties, and the relator to obtain up to 30 percent of the recovery.
- Many cases involve allegedly false claims and statements presented by healthcare providers to government health care programs (e.g., Medicare, Medicaid, TRICARE).
- The volume of such claims is often large; many cases involve thousands, tens of thousands, and even hundreds of thousands of claims.
- Statistical sampling and extrapolation has been used in FCA investigations and litigation to establish the number and amount of allegedly false claims.
- The law remains unsettled on whether and when such evidence is appropriate.

What is Sampling? – Inferential Statistics

- If **time** and **cost** were not factors, we would prefer to evaluate every event in a given population.
- Sampling is the **art** and **science** of selecting a subset of a population, to infer characteristics about the entire population.
- Statistical sampling is often used to reduce the cost and time involved in analysis. For example:
  - Financial and compliance audits
  - Due diligence or verifications
  - Regression analysis and predictive modeling
- The goal is to draw conclusions in a faster, more economical manner, while fully *understanding the limitations of those conclusions*.



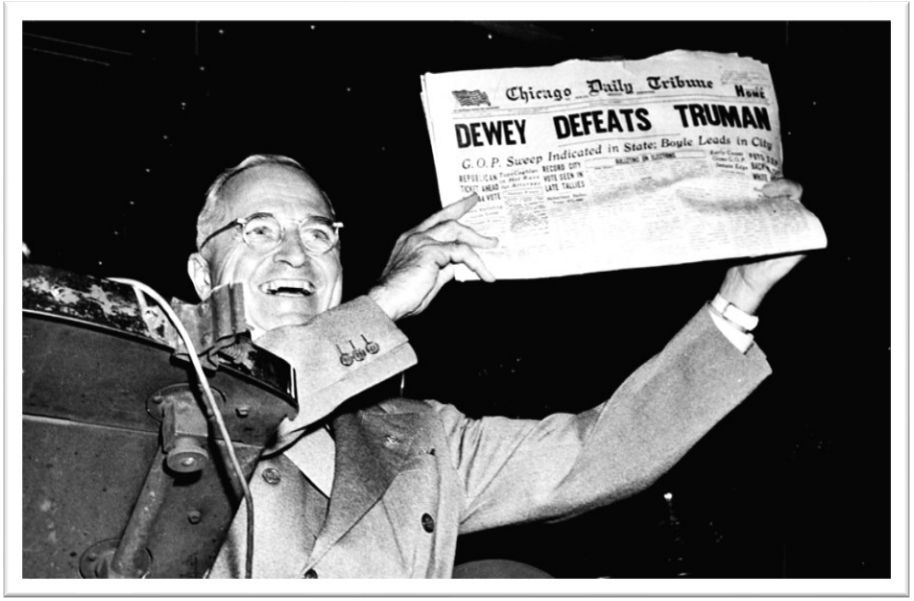
Sampling Vocabulary - Population and Sample

- The **population** is the entire universe in which you are interested. For example:
  - All U.S. citizens around the globe
  - All publicly traded companies as of 1 Jan 2013
  - All claims for medical services submitted by a particular physician in 2009
- A **sample** is a subset from the population.
- Estimates from a sample can only provide valid statistical conclusions about the population from which it is drawn.
- Distinct from **direct evidence**.
- What makes a good sample?

A Good Sample (statistically valid random sample "SVRS")

Among other things…

- **Random**
  - Randomness helps minimize the risk of drawing biased conclusions
- **Large**
  - Larger samples enable more accurate *and* more precise conclusions
- **Pertinent**
  - Includes information only from the relevant population
- **Inclusive**
  - Include information from all groups in the population



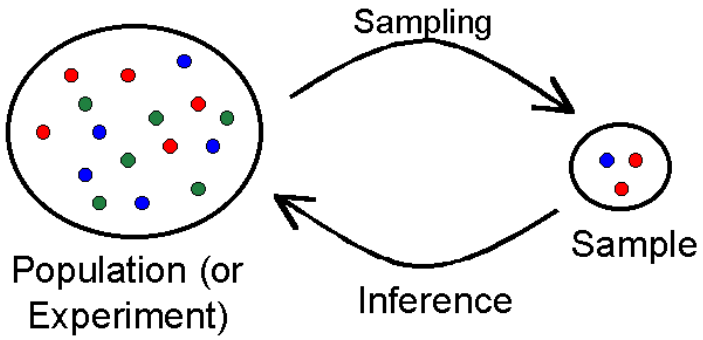
In conducting its exit polls, the Tribune's pollsters contacted people by telephone, assuming telephone users were representative of all voters. In 1948, however, those who owned telephones were politically biased, leading to an incorrect conclusion.

*Drawing a **non-representative sample** or misunderstanding what your sample represents can result in **incorrect inferences from that sample**.*

What Can You Do With a "Good" Sample?

Extrapolation: Projecting the results of your sample onto the entire population.

- Observed ratios (attribute data):
  - Proportion of red M&Ms
  - Proportion of voters who prefer candidate X
  - Failure rate of an audit
- Observed descriptive statistics (variable data):
  - Mean household income
  - Mean overpayment per claim



Extrapolations yield results within a specified **level of significance.**

- Different sample sizes will yield results with different levels of significance
  - If selected properly, larger sample sizes yield greater significance
- **Confidence level** (i.e., 95%, 99%, etc.)
- **Margin of error** or **precision** level (i.e., ±3 percentage points)
- e.g., Candidate X is expected to receive 47% of votes, ±2 percentage points, at a 90% confidence level

Use of Sampling and Extrapolation in FCA Litigation

To satisfy *Rule 9(b)*:

- To allege that at least one specific false claim was (or must have been) presented to the government.
- To allege "reliable indicia" that false claims were presented to the government.

To establish the *falsity* of certain claims:

- When a claim by claim analysis is impractical.
- When a claim by claim analysis is impossible? *See, e.g.*, *United States ex rel. Michaels v. Agape Senior Community, Inc.*, 2015 WL 3903675, at *6–7 (D.S.C. June 25, 2013) (suggesting *in dicta* that sampling and extrapolation may be used to establish liability in FCA cases in which "evidence has dissipated, thus rendering direct proof of damages impossible").

To establish *causation* in certain "causes to be presented" and "causes to be made or used" (*see* 31 U.S.C. § 3729(a)(1)(A), (B)) cases:

- That is, cases in which the government alleges that an individual or entity *caused another individual or entity* to submit a false claim or statement material to one.
- Example: Off label marketing cases.

To quantify *damages*.

Arguments in Support of Sampling

Statutory arguments:

- The FCA is a broad remedial statute.
- The FCA contains no explicit or categorical exclusion of sampling and extrapolation.
- The FCA has been amended several times since courts have permitted sampling and extrapolation in FCA litigation.
- The FCA recognizes "alternate remed[ies]," 31 U.S.C. § 3730(c)(5), including under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, which permits the government to "introduce the results of a statistical sampling study as evidence of the *number* and *amount*" of false claims submitted to a government health care program. 42 C.F.R. § 402.109 (emphasis added).
- The FCA creates liability for knowingly avoiding an obligation to return an "overpayment," 31 U.S.C. § 3729(a)(1)(G), which may often be established through sampling and extrapolation. *See* 42 U.S.C. 1395ddd(f)(3) (permitting a Medicare contractor to "use extrapolation to determine overpayment amounts" if there is a "sustained or high level of payment error" or "educational intervention has failed").

Arguments in Support of Sampling

Policy arguments:

- The FCA is the government's "primary litigative tool for combatting fraud." S. Rep. No. 99-345, at 2 (1986).
- Claim-by-claim proof of falsity is infeasible in cases involving thousands, tens of thousands, and hundreds of thousands of claims.
  - The time and expense required to establish falsity on a claim-by-claim basis may exceed the expected recovery.
  - Without sampling and extrapolation, large scale fraud may be largely un-redressable.
  - Claim-by-claim litigation and trial strains limited judicial resources.

Arguments in Support of Sampling

Caselaw:

- The Supreme Court held that sampling and extrapolation, "like all evidence, is a means to establish or defend again liability" in a Fair Labor Standards Act class action, and that its "categorical exclusion . . . would make little sense." *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 454–55 (2016).
- FCA case law has approved of the use of sampling and extrapolation to establish liability.
  - *United States ex rel. Schmuckley v. Rite Aid Corp.*, 2020 WL 3970201, at *6–10 (E.D. Cal. July 14, 2020).
  - *United States ex rel. Scott v. Ariz. Ctr. For Hematology & Oncology, PLC,* 2020 WL 2059926, at *7–11 (D. Ariz. Apr. 29, 2020).
  - *United States ex rel. Guardiola v. Renown Health*, 2015 WL 5123375, at *1 (D. Nev. Sept. 1, 2015).
  - *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 WL 1926417, at *3–4 (M.D. Fla. Apr. 28, 2015).
  - *United States v. Robinson*, 2015 WL 1479396, at *11 (E.D. Ky. Mar. 31, 2015).
  - *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 567 (E.D. Tenn. 2014).

Arguments Against Sampling

Statutory arguments:

- The FCA addresses individual claims, not generalized fraud.
  - "Not all fraudulent conduct gives rise to liability under the FCA. '[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)).
  - Evidence of an actual false claim is "the sine qua non of a False Claims Act violation." *United States ex rel. Clauson v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002).
  - The FCA is not "an all-purpose antifraud statute," *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672, or "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016).
- The FCA should not be interpreted in a manner that shifts the burden of proof or deprives defendants of due process.
  - Extrapolation shifts the burden of proof on the falsity of the un-reviewed claims in the universe from the government/relator to the defendant. *See* 31 U.S.C. § 37301(d) (requiring proof of "all essential elements" of the FCA cause of action "by a preponderance of the evidence").
  - Extrapolation allows the government/relator to establish the falsity of individual claims that no fact finder has ever evaluated or determined to be false.

Arguments Against Sampling

Policy arguments:

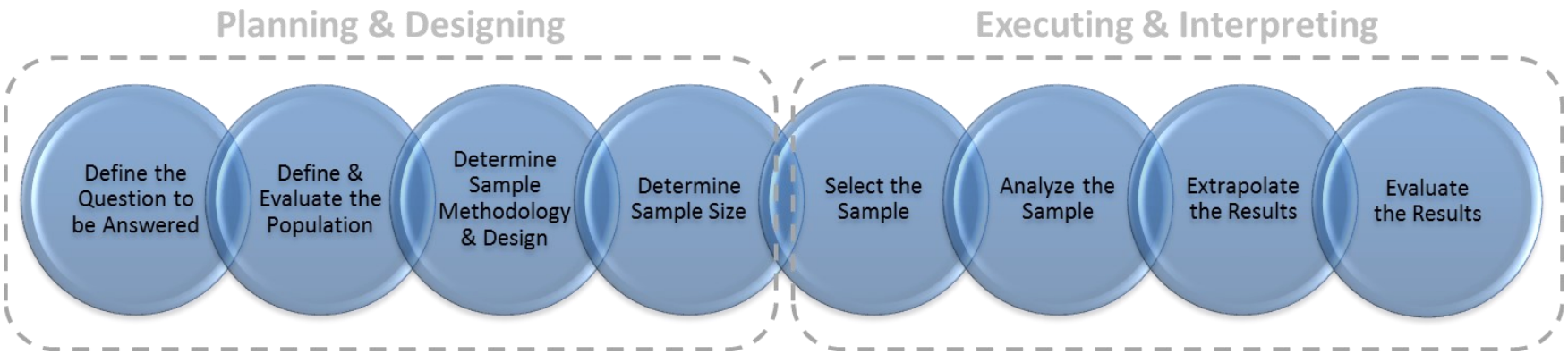
- In certain FCA cases, the standard of falsity is less objective than in others.
- For example, falsity in cases involving medical necessity often turns on a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patients." *United States ex rel. Michaels v. Agape Senior Community, Inc.*, 2015 WL 3903675, at *8 (D.S.C. June 25, 2013). Furthermore, the independent medical judgment of attending and certifying physicians must be accounted for.
- In such cases, individual evaluation of each allegedly false claim is especially imperative.

Arguments Against Sampling

Caselaw:

- The Supreme Court held that sampling and extrapolation could not be used to establish liability in a Fair Labor Standards Act class action in which liability depended on the discretionary employment decisions of hundreds of individual store manager. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338 (2011).
- FCA case law has disapproved of the use of sampling and extrapolation to establish liability.
- Cases:
  - *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *13 (N.D. Tex. June 20, 2016).
  - *United States ex rel. Michaels v. Agape Senior Community, Inc.*, 2015 WL 3903675, at *8 (D.S.C. June 25, 2013).
  - *United States v. Friedman*, 1993 WL 13957433, at *3 & n.2 (D. Mass. July 28, 1993).

Elements of Reliable Sampling – A Framework



- An eight-step approach to statistical sampling;
- Demands attention to **all** eight steps;
- Errors in one step may render an **entire** analysis unreliable, even when all others are performed well.
- Statistical software (e.g., RAT-STATS) alone isn't enough

Best Practices for Employing Sampling

- **When to use sampling?**
  - Determine if sampling makes sense. Are time / cost restrictions involved in reviewing data?
  - Ensure that the statistical expert understands what the sample is being used to establish
- **Well-designed and implemented Policies and Procedures**
  - Ensure the methodology and sampling procedures and clear in advance
  - Statistical oversight can help to ensure reviews conform to the methodology
- **Provide sufficient documentation to replicate and scrutinize each step**
  - "The camera is always rolling" – be prepared for a document request
  - Standardized sampling plans, reports, test work, and training materials can be very helpful
- **Focus on the up-front sample design and planning to avoid execution errors**
  - It is much more difficult to correct errors *after* the sample has been drawn
  - Ask questions to fully understand the population
- **Know when to rely on experts, internally or externally**
  - Clinical, coding, or statistics experts are commonly needed to design and implement analysis

Common Areas for Scrutiny

- Is extrapolation justified (e.g., time and cost constraints, etc.)?
- Is sampling analysis adequately documented and replicable (i.e., due process)?
- What standards/protocols are involved? Are they followed?
- Is the population properly defined?
- Are sample size(s) sufficient and/or calculated appropriately?
- Is the sample properly randomized?
- Is the sample reasonably representative of the population?
- Are the confidence and precision sufficient and/or calculated properly?
- If the sample measured correctly (i.e., error rate, damages, etc.)?
- Do other systematic errors exist that might inject bias?

Sampling for Specific Issues of Liability

Medical necessity

- Hospice: Falsity in hospice cases depends on prognostication about likely life expectancy. *E.g.*, *United States v. Aseracare, Inc.*, No. 2:12-cv-00245 (N.D. Ala.).
- Hospital Admission: Falsity in hospital admission cases depends on prognostication about the length of time that patients are likely to require inpatient care (more than "two midnights"?). *E.g.*, *United States ex rel. Berntsen v. Prime Healthcare Services, Inc.*, No. 2:19-cv-02242 (C.D. Cal.).
- Skilled Nursing Facility: Falsity in SNF cases depends on individual physician assessments of patients' current and expected future conditions. *E.g.*, *United States ex rel. Martin v. Life Care Ctrs. of Amer., Inc.*, No. 1:12-cv-00064 (E.D. Tenn.).
- Cardiologist: Falsity in cardiovascular procedures cases (e.g., stents, angioplasty, atherectomy) depends on individual physician assessments of the severity of patients' diseases. *E.g.*, *United States ex rel. Taylor v. Institute of Cardiovascular Excellence*, No. 5:11-cv-00406.

Discussion

- Is sampling and extrapolation an appropriate means of establishing falsity in these cases?
- Some subset of them?

Sampling for Specific Issues of Liability

Causal Connection for Off-Label Marketing

- The FCA provides that any person (or entity) that "presents, or *causes to be presented*" a false or fraudulent claim or statement material to one is liable.
- Generally, the legal theory in off label marketing cases is that a drug manufacture's false or fraudulent advertising caused physicians to write prescriptions for drugs that Medicare does not cover (i.e., drugs prescribed for off label uses lacking support in official compendia), thereby causing pharmacies to submit claims for non-covered drugs to government healthcare programs.
- Brief discussion of recent cases:
  - *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57–58 (1st Cir. 2017) (affirming summary judgment because after "six years of litigation, realtors' only proffered evidence of actual false claims was aggregate data reflecting the amount of money expended by Medicaid for pediatric Geodon prescriptions (an off-label use) between January 2008 and March 2012").
  - *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1037–40 (C.D. Cal. 2016) (denying summary judgment based in part upon expert consideration of Medicare payment data and statistical estimation that "43,092 claims for off-label use of Thalomid were presented to Medicare between 1999 and 2005").
  - *See also In re Neurontin Marketing & Sales Practices Litig.*,712 F.3d 60 (1st Cir. 2013) (holding that plaintiffs could use aggregate data together with strong circumstantial evidence to overcome summary judgment on the distinct issue of whether there was a causal link between fraudulent marketing and demonstrated off-label prescriptions in the distinct context of a civil RICO case).

Sampling for Specific Issues of Liability

Other Issues

- Billing for services not rendered?
- Up-coding?
- Billing for services provide by unlicensed providers?
- Claims allegedly tainted by kickbacks or Stark Law violations?
- [Others?]

Current Issues of Sampling in FCA Cases

- Do the number and type of defendants named in an FCA action impact the appropriateness of sampling and extrapolation?
  - Single health care provider versus group?
  - Single health care entity versus network?
  - Local versus nationwide network?
- Should threshold facts be found before sampling and extrapolation may be used to establish liability?
  - In *Loughren*, a health insurance company caused over 450,000 insureds to submit false claims for Social Security Disability Insurance (SSDI). 604 F. Supp. 2d at 260–61. The company filed a *Daubert* motion to preclude proof of those claims by sampling and extrapolation. At the time of the *Daubert* motion, it was unclear whether each insurance examiner made a "separate subjective evaluation" about "the decision whether to require a claimant to file an application" for SSDI, or whether the company "had a *general policy* of requiring a claimant to file an application" before they were entitled to benefits. Evidence at trial suggested that the company had a "*policy and practice* of coercing its insureds" to request SSDI "as soon as they were disabled for six months" regardless of other eligibility considerations. Relying on those findings, the district court concluded that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate."
- Should the government/relator be required to "link" allegedly fraudulent corporate practices (sometimes called "scienter evidence") to individual claims in the sample?
  - *See United State v. Aseracare, Inc.*, 938 F.3d 1278, 1305 (11th Cir. 2019) (holding that the government must be able to "link" general evidence of scienter to "the specific 123 claims" in the sample).

Parting Thoughts and Questions

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Appendices & Additional Resources

Additional Resources

- Statistical Sampling & Rat-STATS Blog: http://forensus.com/rat-stats-and-sampling-blog/
- Medicare Program Integrity Manual (MPIM); Chapter Eight, Statistical Sampling and Overpayment Estimation; https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c08.pdf
- AICPA Generally Accepted Audit Standards & Sampling Guidance;
- OIG Corporate Integrity Agreement FAQs; https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp
- OIG Provider Self-Disclosure Protocol; https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp

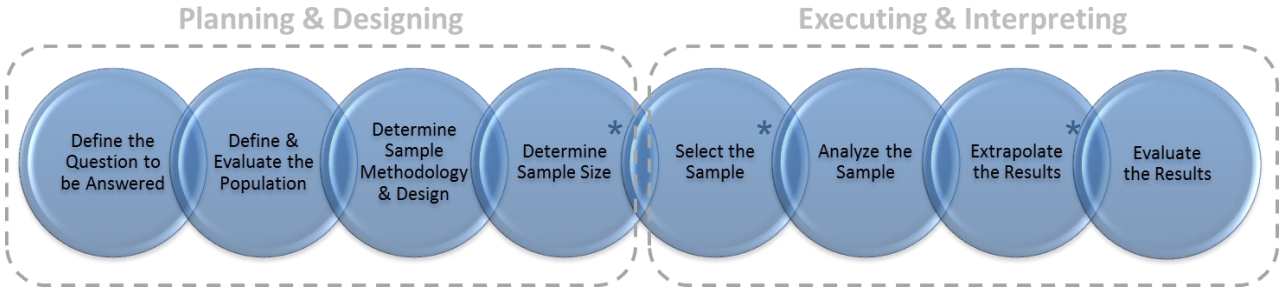
Before You Begin, Prepare Your Sampling Plan

Define the following:

- **Population of Interest** *(POI) This can help you prepare your request for data*
- **Sampling Unit** *Population of interest is composed of all possible sampling units*
- **Sampling Frame** *Population from which the sample is drawn (explain if not equal to POI)*
- **Sample Size Minimum** *or any other procedural requirements/thresholds*
- **Required Level of Precision and Confidence** *possibly 95% confidence ±2% precision*
- **Sample Design** *Simple, Stratified, Clustered, etc. Specify strata or cluster criteria*
- **Source of Random Numbers** *often RAT-STATS*
- **Method of Selecting Sampling Units** *Ensure random numbers are applied without bias*
- **Procedures for Missing Data** *Typically failures, however spares may be appropriate*
- **Estimation Methodology** *Also referred to as extrapolation methodology*

RAT-STATS Statistical Software

- RAT-STATS is statistical software developed by the U.S. Government
  - Free software available online, along with user-guide and companion-manual
  - Key tool used by the government to help identify and quantify improper claims
- Functionally, RAT-STATS is a calculator with **three main functions**:
  - Calculating sample size
  - Generating random numbers to aid sample selection
  - Extrapolating (estimating) results of the sample to a broader population
- RAT-STATS is a tool to be used <u>in conjunction</u> with a broader statistical strategy



* These steps involve using RAT-STATS

How is Sampling Different from Direct Evidence?

Taking a look at *United States ex rel. Ruckh v. Genoa Healthcare*

Summary of Case: In *Ruckh*, the relator alleged the defendant engaged in "flagrant upcoding" of charges to Medicare and Medicaid at fifty-three medical facilities.

Use of Statistical Sampling: The relator sought the court's approval to admit expert testimony on statistical sampling due to the large volume of discovery, however the sampling had not yet occurred. The defendant challenged the proposed use of statistical sampling, arguing that the claims should be analyzed individually even though it would be more cumbersome. The court rejected this reasoning because the case cited by the defendant involved a much smaller number of claims than the one in the case at hand.

Holding: The court held that it was not appropriate to rule on the admissibility of statistical evidence before such evidence had even been prepared and denied Relator's motion.

- *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 WL 1926417, at *1-3 (M.D. Fla. Apr. 28, 2015).

Use of Sampling and Extrapolation in FCA Litigation

U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.

Summary of Case: Relators brought an action against Agape Senior Community, Inc. alleging that Agape fraudulently sought reimbursements from Medicare, Tricare, and Medicaid for hospice care and general inpatient services. There were over 50,000 claims at issue and it was clear that extensive time and money would be spent having experts review all the files. However, the court ruled that statistical sampling could not be used to prove damages. The parties reached a settlement of $2.5M and avoided the necessity of a bellwether trial. Then the Government attempted to veto the settlement because, using a form of statistical sampling and extrapolation, it estimated that the total potential damages would be around $25M.

Use of Statistical Sampling: The court had already decided to disallow the use of statistical sampling to prove damages because all the evidence was still available and intact (unlike some other cases) and each claim had to be subjected to the fact-dependent determination of whether the services provided were medically necessary.

Holding: The Government has unreviewable veto authority to reject a settlement in a *qui tam* action in which it has declined to intervene. The use of statistical sampling to prove liability and damages in the present case had been rejected and the court declined to allow the government to use it when the parties could not.

- *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 WL 3903675 (D.S.C. June 25, 2015).

Arguments in Support of Sampling
U.S. ex rel. Schmuckley v. Rite Aid Corp.

Summary of the Case: The relator brought an action against Rite Aid alleging it submitted false claims to Medi-Cal by not complying with the required documentation and certification requirements for certain prescriptions with heightened restrictions.

Use of Statistical Sampling: Rite Aid argued that the case at hand required an individualized determination for each claim as to whether the prescription was medically necessary and that therefore statistical sampling was inappropriate. The court rejected the argument. The Rite Aid case did not require individual assessment of medical necessity because the only thing that needed to be reviewed to determine the claim's falsity was whether Rite Aid had completed the requisite documentation and certification. Additionally, a huge number of claims were at issue—almost four million—meaning statistical sampling could be particularly useful in conserving resources. The court then analyzed defendant's objections under Rule 702 and *Daubert* and found the evidence met the criteria.

Holding: The court held that the statistical sampling and related expert witness evidence met the criteria set forth in Federal Rules of Evidence Rule 702 and *Daubert* and that statistical sampling was appropriate in the present case.

- *U.S. ex rel. Schmuckley v. Rite Aid Corp.*, No. 2:12-cv-01699-KJM-EFB, 2020 WL 3970201, at *1 (E.D. Cal. July 14, 2020).

Arguments in Support of Sampling
U.S. ex rel. Scott v. Ariz. Ctr. for Hematology and Oncology

Summary of Case: The relator, a former billing manager for the defendant, brought an action against Arizona Center for Hematology and Oncology for at least 4,000 claims related to billing for scans that allegedly were not performed. Relator hired two experts, Dr. Wyner a statistician and Dr. Noyes a physician expert in medical billing.

Use of Statistical Sampling:

- → Defendant challenged Dr. Wyner's qualifications claiming that he was unqualified to opine on medical billing. The court found that the statistician did not have to be a healthcare billing expert and that he was qualified according to the Medicare Program Integrity Manual.
- → Defendant attacked the statistician's methodology for his failure to disclose the random seeds and sampling frames, not having representative samples, and containing errors. The court did not find the errors fatal; rather, it said "the failure to keep such documentation does not necessarily render a sample invalid, but it can make the resulting estimate more difficult to defend" and that the statistician had defended his methodology to the point where the trier of fact was the appropriate judge of the matter.
- → Defendant also argued that the claims involved fact-specific, subjective determinations by treating physicians and therefore liability could not be established through statistical sampling. The court found that the medical records themselves showed that the patients were not administered the scans for which the defendant, and therefore no individual, case-by-case review was required.

Holding: The court held that if the statistical evidence meets the reliability standards set forth in the Federal Rules of Evidence it may be admitted. Since the evidence presented did meet such standards and there were issues of material fact, summary judgment was denied.

- *U.S. ex rel. Scott v. Ariz. Ctr. for Hematology and Oncology*, No. CV-16-03703-PHX-DGC, 2020 WL 2059926, at *1, *5, *10 (D. Ariz. April 29, 2020).

Arguments in Support of Sampling
U.S. ex rel. Guardiola v. Renown Health

Summary of the Case: Relator sued Renown Health alleging that Defendant submitted false inpatient reimbursement claims that were higher than they would have been if correct. During the discovery phase, Defendant challenged as irrelevant both Relator's statistician's interpretation of defined term "zero-day stay" and attempt to include additional data in her sample based on the reinterpretation. The relator responded that her reinterpretation was necessitated by the fact that some claims would be excluded that should not be and was relevant because it affected the accuracy of her samples.

Holding: The court held that, because the challenge occurred during discovery and because the evidence could render the expert's testimony more reliable and accurate at trial, the evidence was relevant and that the court must permit the discovery. The court opined that whether it would be admissible at trial was a different question and not appropriately resolved at this stage of the litigation.

- *U.S. ex rel. Guardiola v. Renown Health*, No. 3:12-cv-00295-LRH-VPC, 2015 WL 5123375, at *1 (D. Nev. Sept. 1, 2015).

Arguments in Support of Sampling
U.S. v. Robinson

Summary of the Case: Relator alleged that Dr. Robinson submitted over 25,000 claims and was reimbursed more than $1.4M for medically unnecessary optometry services provided to nursing home patients. The case went to trial and the jury found that Dr. Robinson submitted 11,085 false claims. The trial court denied Dr. Robinson's motion for a new trial and the doctor appealed contending that the use of statistical sampling was inappropriate and that it prevented the jury from properly calculating damages.

Holding: The court refused to address the first issue because it was raised for the first time on appeal. As for the second issue, the court held that the jury's damages calculation was reasonable because it corresponded with mathematical calculations presented in the evidence.

- *U.S. v. Robinson*, 705 Fed.Appx. 458, 458-59 (6th Cir. 2017) (memorandum opinion).

Arguments in Support of Sampling

U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.

Summary of Case: Relators brought an action against Life Care alleging that, regardless of medical necessity, it pressured its therapists to target the highest RUG levels (which had the highest Medicare reimbursement rate) and increase the average length of stay of patients, ideally exhausting all 100 days of the patient's Medicare skilled nursing benefit, thus maximizing reimbursements from Medicare, Medicaid, and Tricare.

Use of Statistical Sampling: Statistical sampling and extrapolation may be appropriate in cases like this where the large number of claims makes it impractical and costly for the government to conduct a case-by-case review. Here, parties were faced with reviewing 154,621 total claims for 54,396 patients at 82 facilities. Additionally, it was appropriate in Life Care because the government was seeking to prove an objective falsehood, meaning it did not require a case-by-case review of the subjective medical necessity of the therapies.

Holding: Statistical sampling may be used to prove claims brought under the FCA involving Medicare overpayment, but it does not and cannot control the weight that the fact finder may accord to the extrapolated evidence

- *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F.Supp.3d 549, 553 (E.D. Tenn. 2014).

Arguments in Support of Sampling

U.S. ex rel. Integra Med Analytics, LLC v. Creative Sols. in Healthcare, Inc.

Summary of Case: Relator brought an action against Creative Solutions, which owned and operated a network of skilled nursing facilities, alleging over $94 million in Medicare false claims and $2.01 million in Medicaid false claims. Specifically, the Relator alleged that Creative Solutions pressured therapists to use the highest level of rehab regardless of need, encouraged fraudulent billing practices, and created a policy of keeping patients for the maximum 100-day Medicare reimbursement period (again, regardless of need).

Use of Statistical Sampling: The district court approvingly noted the relator's reliance on both quantitative and qualitative analysis. In particular, the relator was able to leverage witness interviews combined with a robust statistical analysis to describe in detail the scheme Creative Solutions used to maximize reimbursements through the submission of false claims.

Holding: The court held that the combined statistical evidence and witness interviews were enough for it to find that the relator had plausibly pled the scienter element. (The witness interviews described institutional processes, such as having to justify *not* assigning a patient to the Ultra High rehab.) The court also permitted a claim to move forward despite the fact that the evidence may have been insufficient to prove the falsity element, stating that that determination was more appropriately left for the summary judgment phase.

- *U.S. ex rel. Integra Med Analytics, LLC v. Creative Sols. in Healthcare, Inc.*, No. SA-17-CV-1249-XR, 2019 WL 5970283, at *1 (W.D. Tex. Nov. 13, 2019).

Arguments Against Sampling
U.S. ex rel. Wall v. Vista Hospice Care, Inc.

Summary of Case: Relator brought an action against Vista Hospice Care, Inc., aka Vistacare, for Medicare Hospice Benefit false claims. Specifically, the relator, a social worker employed at one of Vistacare's locations in Texas, alleged that Vistacare certified Medicare Hospice Benefit ineligible patients as eligible and engaged in kickback schemes while certifying compliance with the Anti-Kickback Statute.

Use of Statistical Sampling: Relator engaged an expert statistician, Dr. Kriegler, and an expert hospice physician, Dr. Steinberg, to prepare reports that the relator could use as evidence. The hospice physician reviewed and concluded from 291 patient files that a large percentage of the patients were not eligible for the hospice benefit at least part of the time they were receiving it. The statistician then used the physician's report to draw conclusions about the probable number of false claims.

Holding: Statistical sampling was inappropriate here because the determination of hospice eligibility is "inherently subjective, patient-specific, and dependent on the judgment of involved physicians." Additionally, the statistician did not use reliable methods: he did not start with a random sample, did not account for variables the physician identified as important, and misclassified patients during stratification which affected probability for selecting certain patients for the sample.

- *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833, at *1 (N.D. Tex. June 20, 2016).

Sampling for Specific Issues of Liability
U.S. v. AseraCare Inc.

Summary of the Case: Government sued AseraCare for falsely certifying patients for hospice care (for Medicare purposes, hospice care should only be certified when a patient's life expectancy is < 6 months). In 2014, the parties filed cross-motions for summary judgment. The case involved 2,181 patients, so the Government used statistical sampling to evaluate the claims and then sought to extrapolate from its findings. AseraCare argued that the Government's evidence, including expert testimony from a physician, did not support a finding of falsity or knowledge as required by the FCA statute. The court held that the evidence was sufficient to create a dispute of material fact and therefore summary judgment was denied. In doing so, the court stated that as to the falsity element, the FCA "requires proof of objective falsehood."

The Eleventh Circuit confirmed this interpretation of the FCA falsity element in 2019 while ruling on an appeal of the trial court's decision to order a new trial and *sua sponte* grant summary judgment in favor of AseraCare. The court sought to distinguish objective falsity from disagreeing reasonable professional opinions by two different physicians and held that the FCA required objective falsity. In the context of the case, that meant that the plaintiff must show that the "facts and circumstances surrounding the patient's certification are inconsistent with the proper exercise of a physician's clinical judgment."

- *U.S. v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254, at*1 (N.D. Ala. Dec. 4, 2014); *U.S. v. AseraCare Inc.*, 938 F.3d 1278 (11th Cir. 2019).

Sampling for Specific Issues of Liability
Limits on *AseraCare*

In 2020, both the Third and Ninth Circuit rejected the Eleventh Circuit's *AseraCare* objective falsity standard.

Care Alternatives–In the Third Circuit case, *Care Alternatives*, the court rejected the *AseraCare* suggestion that a physician's clinical judgment could not be false. Instead, it interpreted the plain language of the FCA to mean that falsity required a determination as to whether the claims submitted met the conditions for reimbursement established by the government, but did not require scienter on the part of the physician (since it was a separate element). Applying the broader definition to the case at hand, the Third Circuit held that to satisfy the falsity element the relators had to show either that the physician did not certify a terminally ill patient or that the certification did not meet the requirement that the clinical information supporting the diagnosis accompany the certification.
- *U.S. ex rel. Druding v. Care Alternatives*, 952 F.3d 89 (3rd Cir. 2020)

Gardens Regional Hospital– In the Ninth Circuit case *Gardens Regional Hospital and Medical Center*, the Relator alleged that the defendant filed false Medicare claims certifying inpatient hospital stays as medically necessary. In *Gardens Regional Hospital and Medical Center*, the court held that the FCA does not require objective falsity and that a doctor may give a false clinical opinion if he knows it is false or gives it in reckless disregard of the truth. The Ninth Circuit attempted to reconcile this view with *AseraCare* by stating that *AseraCare*'s objective falsity interpretation was limited to situations involving multiple reasonable but conflicting physicians' opinions of medical necessity with no other evidence to assist in determining which opinion(s) (if any) are false.
- *U.S. ex rel. Winter v. Gardens Reg'l Hospital and Med. Ctr., Inc.*, 953 F.3d 1108, 1113 (9th Cir. 2020).

Sampling for Specific Issues of Liability

U.S. ex rel. Booker v. Pfizer, Inc.

Summary of the Case: Relators argued that Pfizer had promoted the drug Geodon for off-label uses in violation of 31 U.S.C. § 3729(a)(1)(A). In doing so, Relators provided evidence in the form of government aggregate expenditure data.

Use of Statistical Sampling: Relator attempted to use aggregate data alone to get past the summary judgment phase without identifying a single false claim. The court said that without specific information regarding the medical providers who submitted these claims, the approximate time period during which they were submitted, amounts, or circumstances, the evidence did not present an issue of material fact and was insufficient to get beyond summary judgment. “Merely alleging that a scheme was wide-ranging [and] that a [false] claim was presumably submitted . . . will not suffice;” an actual false claim must be presented.

Holding: The court held that the Relators could not use aggregate data alone to prove the existence of false claims in an FCA case.

- *U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57 (1st Cir. 2017).

Sampling for Specific Issues of Liability

U.S. ex rel. Brown v. Celgene Corp.

Summary of the Case: Relator, an employee of Celgene, sued Celgene alleging that it was engaged in promoting two of its drugs for off-label uses broader than those approved by the FDA (and hence not reimbursable under Medicare, Medicaid, and Tricare). Celgene moved for summary judgment claiming that Relator could not prove a causal connection between the off-label promotion and physicians prescribing the drug. In determining whether Brown was able to prove causation, the court applied the "substantial factor" test, which asks "whether presentment of Medicare claims was a foreseeable and natural consequence of Celgene's conduct." The court found that based on Brown's testimony regarding her work for Celgene (which involved promoting the drugs for off-label uses), testimony by other sales representatives, and expert testimony regarding data showing a link between sales contacts and prescriptions written, there was a connection between Celgene's promotional efforts and the rate at which physicians prescribed the two drugs. The court held that Celgene's claims for non-"medically accepted" uses were false because under Medicare rules, Medicare Part D covered drugs are only those that have "medically accepted indications" making them statutorily ineligible for reimbursement.

Use of Statistical Sampling: Brown hired an expert witness to analyze the data and determine whether it supported a conclusion that Celgene's promotional efforts resulted in more physicians prescribing the drugs for their off-label uses. The expert found that physicians who had greater contact with Celgene's representatives prescribed the two drugs at a higher rate and the physicians with less contact, thus helping prove a causal link between the off-label promotion and the filing of false claims.

Holding: The court held that Brown presented sufficient evidence to show that Celgene's actions caused claims to be filed for off-label uses of the two drugs and that some of the claims were false. Summary judgment as to the Medicare claims was denied.

- *U.S. ex rel. Brown v. Celgene Corp.*, 226 F.Supp.3d 1032, 1036 (C.D. Cal. 2016).

Sampling for Specific Issues of Liability
Neurontin Cases

Summary of the Case: (Action brought under RICO and local consumer fraud statute.) Plaintiffs alleged that Pfizer marketed the drug Neurontin for off-label conditions/uses, including bi-polar disorder, that it was not actually effective at treating.

Use of Statistical Sampling: Plaintiffs hired an expert to prepare a written report using regression analysis that showed that almost all of the Neurontin prescriptions for bi-polar disorder (one of the off-label conditions) resulted from Pfizer's off-label marketing efforts. The district court originally held that the report was insufficient to evidence causation because an individual assessment of each claim was needed to see if the drug was actually ineffective to treat the off-label condition for each individual patient.

Holding: The circuit court reversed finding the written report sufficient and because it was supplemented with evidence from clinical trials showing the drug was ineffective for that use. The court held that aggregate data combined with other strong circumstantial evidence could be used to prove the existence of a causal link (but-for causation) between fraudulent marketing and prescriptions being written for off-label uses and reversed the summary judgment for Pfizer on the RICO claim.

- *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 60, 62 (1st Cir. 2013).