

# What is billing compliance in clinical research?

Billing compliance ensures all services in a trial are paid for, working to reduce double billing and preventing billing services not covered by the trial or are not medically necessary for the participant.

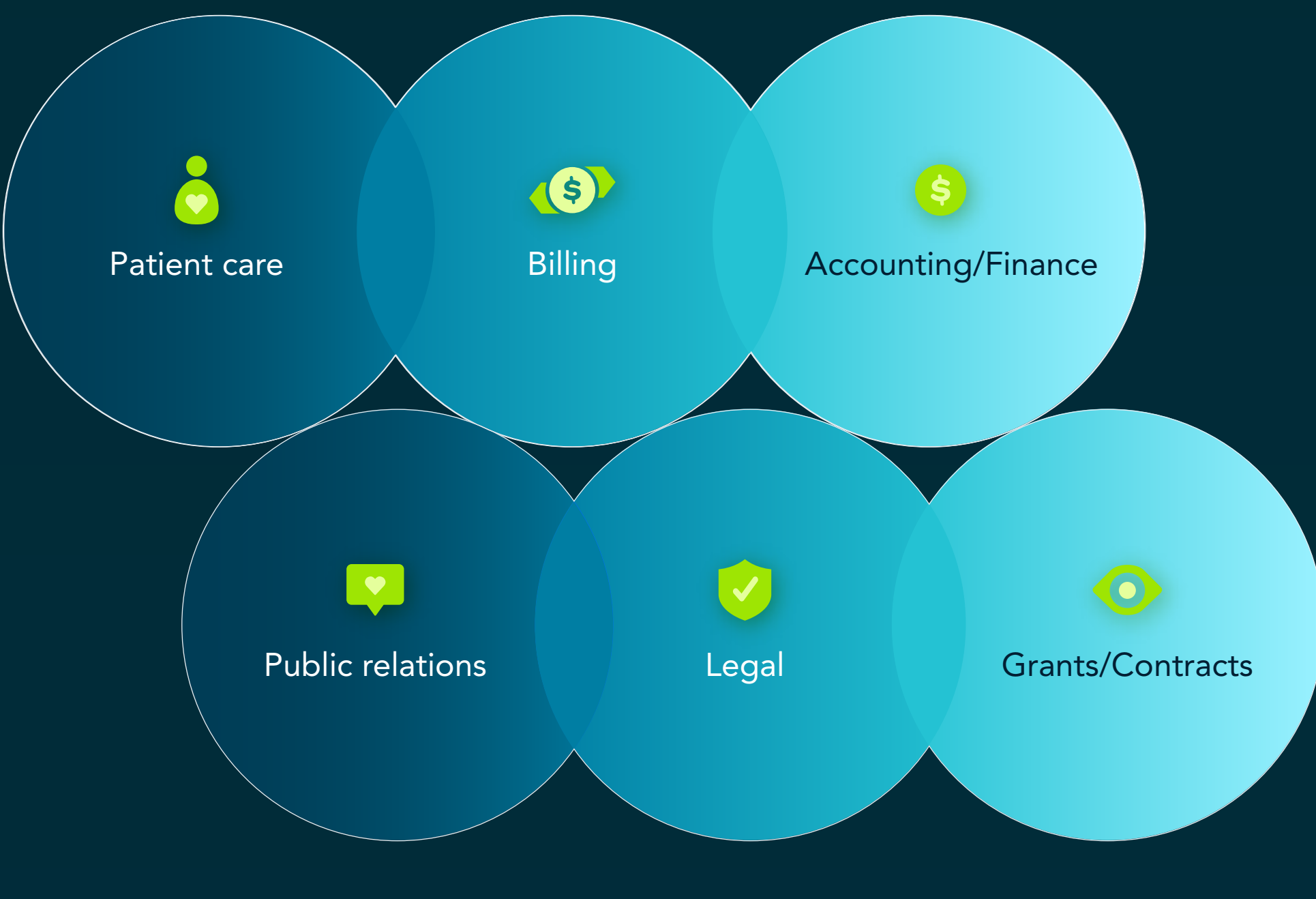
## How does non-compliance happen?

It is largely due to lack of understanding<sup>1</sup>. The clinical billing requirements that must be met include:

No double billing at the site level	Medical documentation supports coding
Research modifiers, diagnosis codes, condition codes, and NCT#* must be in place	Transparent documentation from the sponsor

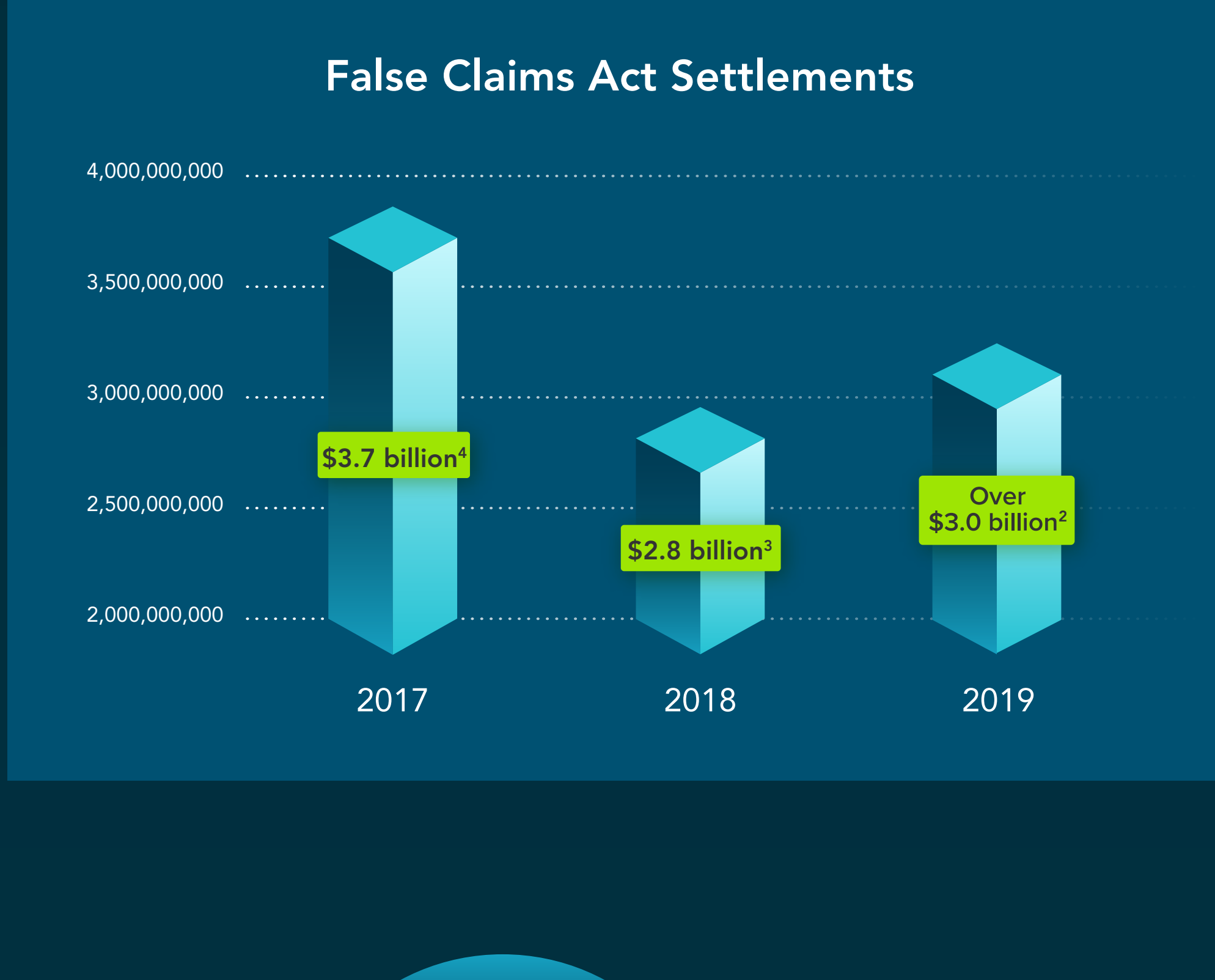
\*national clinical trial number

Areas of clinical research affected by non-compliance:



## Non-compliance can also be costly to an organization.

From the False Claims Act Cases, the Justice Department recovered in settlements:



More than **\$62 billion** since 1986<sup>2</sup>

Additionally, some sites have filed settlements, and the fines show just how much organizations are affected. Sites have settled for improper billing or overbilling for fines up to \$3.39 million. In addition to the fines sites faced, a site's reputation can face severe backlash following the settlements<sup>1</sup>.

The punishment for violating the False Claims Act is hefty.

It is up to **3 times**

the amount of the initial violation

An additional penalty up to

**\$21,916**

per violation<sup>5</sup>

### In 2016:

US hospitals submitted **\$3 trillion** worth of medical claims; **\$262 billion** of the charges were initially denied<sup>6</sup>.

**63%**

of these claims eventually recovered

**\$118**

is the average cost to dispute each claim

**\$8.6 bil**

in total administrative costs

## What is coverage analysis?

Coverage analysis is a review to determine if a research study is eligible to receive Medicare coverage and outlines what items and services performed as part of the research study should be billed to Medicare.

Questions coverage analysts answer:

Is my institution at risk of billing compliance problems?

How are we paying for this service?

Does this study even qualify for Medicare coverage?

How will the billing process affect your patients?

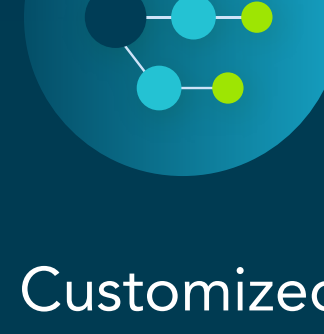
What to look for in your coverage analysis team:



Deep expertise



Knowledgeable, committed, and professional



Customized solutions



Region-specific



Rapid turnaround



Unmatched value