2022 | Issue 7

Physicians office Resource

Resources for You, Your Patients, & Your Practice

HELPING PATIENTS HELP THEMSELVES ONLINE

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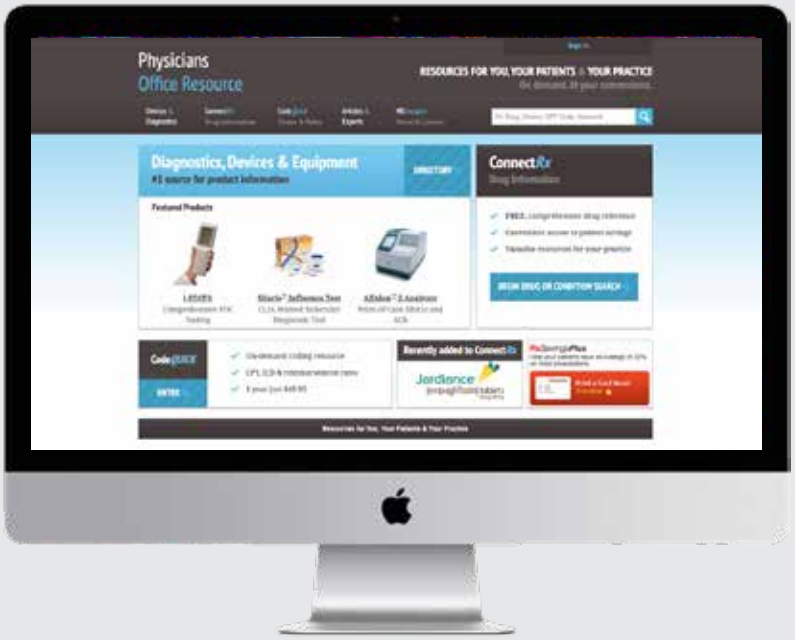


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PUBLISHED BY
Medical Education Resources, LLC

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HELPING PATIENTS HELP THEMSELVES ONLINE

it's becoming important for physicians to not only be the conduits towards viable health information, but also to help patients establish good searching habits for when they come across health information on their own time. Physicians cannot dictate what their patients will read and see outside of the office, but by giving them the tools to sniff out what's good and what probably needs a second opinion, they greatly reduce the number of faulty accidents and misunderstandings.

—

PAGE 6

14

HAVE YOU INTENTIONALLY OR UNINTENTIONALLY BECOME A HIGH COMPLEXITY LAB

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CLIA allows clinical laboratories to modify their FDA-approved tests, and even to develop their own tests, known as laboratory-developed tests (LDTs), as long as they follow the requirements to validate the performance characteristics of their modified or in-house developed tests.

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LEGITIMATE QUESTION: IS IT POSSIBLE TO FIND TRUSTWORTHY FINANCIAL ADVICE?!

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For those still looking for financial planning and other specific financial advisory services, we'll lay out some considerations which we hope are helpful. Before diving deeper into specific services, let's look at some typical services needed at various career stages in medicine.

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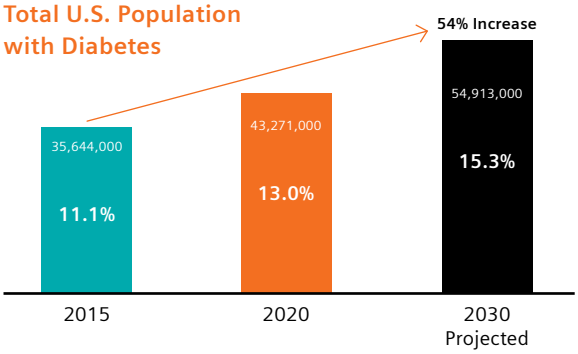


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1. Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.

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Helping Patients Help Themselves Online

BY DLYAN CHADWICK

These days, virtually any brick and mortar service has its own internet doppleganger. One can attain a college degree by attending online classes, stream movies directly from the source and of course, there's Wikipedia, the online staple that's put the final nail in the coffin of the door-to-door Encyclopedia industry. And while there's seemingly no end to the wealth of information afforded to us on the internet, that information does come at a price: internet "quality control" is spotty at best.

Now, that's well and good, likely entry level information to anyone who's ever written a term paper or sought out unbiased information in a Honda forum...but then again, internet literacy isn't always a straightforward metric. In an article by Tanya Fenke MD, (Dr. Google Should Be Sued for Malpractice. Here's Why), the author illustrates the inherent problem of taking all our health concerns to Google, namely that internet sources quickly become outdated, are biased towards their benefactors and constituents, aren't often written by healthcare professionals and often lack traceable references. In fact, as the title dictates, she suggests that if Google were a physician, he or she should be sued for malpractice, based on the number of problems that disseminating false information causes (no word on Dr. Pepper and Dr. Feelgood's prospects at the time of publication).

While I wholeheartedly agree with Fenke's assessment, that Google, or an internet search, isn't a sustainable replacement for actual medical advice from an actual, living, breathing medical professional, I also realize the dilemma of Google's involvement in everything. The trends of internet ubiquity aren't going to slow, nor will Google's lumbering ascent into total control of the internet cease. This isn't glass half-empty philosophizing either, just the acceptance that if/when (more like when) the machines finally do take over, we can assume Google will be in the mix somewhere.

Instead, it's becoming important for physicians to not only be the conduits towards viable health information, but also to help patients establish good searching habits for when they come across health information on their own time. Physicians cannot dictate what their patients will read and

Ultimately, we shouldn't recognize Google as anything even remotely like a doctor and should recast it for what it really is: **"a huge repository of information, scrupulously indexed and largely unregulated."**

Objectivity and Bias

It can be difficult to look objectively at one's own symptoms, especially when emotions are running strong and influencing one's actions. In this regard, internet searching along various strings of keywords can push the user towards a "self-diagnosis" that is biased or at the very least a little skewed. This also introduces what I call the "WebMD" effect in which a person goes down the internet rabbit-hole of reading all symptoms associated with a certain disorder and slowly convinces themselves that they indeed have the disorder. No one is immune to momentary flashes of anxious grandiosity.

Furthermore, there's a wealth of "for profit" sources out there, posing as viable health professionals, even when they're not. Wary patients should be mindful of any sites with corporate sponsors, as the information contained may just be a sideways plug to get you to buy a miracle product or to sell you on an affliction you don't actually have. Solid health information is a right, and shouldn't market you towards buying anything new.

Experience and Credibility

It goes without saying, but a number of those dispensing health care information are just writers….not doctors (this one included). In this regard, knowing exactly where a source comes from can be what will set off the "nonsense meter" right away. Patients should look for the credentials of an author who's dispensing health care information, ensuring that they're actual, medically licensed doctors. Even so, it's not uncommon for professionals to get their articles ghost written by off-site writers. Patients should assume that any information coming from a source that doesn't identify as a physician should probably not be regarded at all, and those that come from doctors, should be carefully vetted before following up on them.

Sources and Citations

In print, most must cite their sources, but on the internet, and it can be a bit more difficult to truly regulate this principle. If a site doesn't cite the sources of its claims, or if they're especially absolute or broad and sweeping, one should maintain their skeptic senses a bit. Information can be sensationalized to drive ratings and page views to a site, and often take claims and facts out of context, specifically to fit their own content agenda. If a site doesn't provide sources for its health care advice, isn't from a health sanctioned organization or contains many sources from less credible sources, patients shouldn't accept the information sight unseen. Remember, if a site doesn't want readers to know where they got their stories, at best they likely don't have anyone's best interests in mind and at worst, could be hiding something.

Encourage the In-Person Follow Up

Fortunately, physicians still have the ultimate, and most credible, say in directing patients towards quality health care information. Besides endowing them with a dose of healthy skepticism towards online health information (and let's be honest, it's a good trait to have in an election year too), it's important to remind them that they can always follow up directly with you, a primary health care source, about anything unclear. Not only does this type of outreach send the message that you're there to help and guide them in their healthcare journey, but also establishes a precedent for always checking up with a qualified source before taking anything to heart.

Ultimately, we shouldn't recognize Google as anything even remotely like a doctor and should recast it for what it really is: "a huge repository of information, scrupulously indexed and largely unregulated." Patients and users still have the power.

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1711



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CHEMISTRY ANALYZERS



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HAVE YOU INTENTIONALLY OR UNINTENTIONALLY BECOME A HIGH COMPLEXITY LAB?

**BY IRWIN Z. ROTHENBERG, MBA, MS, CLS(ASCP),
TECHNICAL WRITER /QUALITY ADVISOR, COLA RESOURCES, INC.**

Introduction

There may be circumstances when laboratories consider the option to modify an FDA-cleared or approved test system. These may be due to the specific needs of the population served; or based on cost/benefit analyses of instrumentation and reagent use; or based on the logistics of in-house testing capabilities. CLIA allows clinical laboratories to modify their FDA-approved tests, and even to develop their own tests, known as laboratory-developed tests (LDTs), as long as they follow the requirements to validate the performance characteristics of their modified or in-house developed tests.

However, it is important to realize when considering modification of a test procedure that the modified use of a test system defaults the test to the high complexity testing category under CLIA regulations, and as a result, the testing site must meet all applicable CLIA requirements for high complexity testing. These requirements include establishing performance specifications that validate that the LDTs, and the modified standard methods are fit for the intended use, and that the lab has personnel qualified to perform high complexity testing. Thus, decisions to modify test procedures or use must be made with full awareness of the consequences for the laboratory operation.

What does test system "modification" mean?

Modification means producing results via test systems not yet approved by the FDA; as well as applying these test results in a way other than that described in the intended use, precautions, limitations, or other sections of the manufacturer's instructions.

Modifications to existing FDA-approved test systems include:

1. Using instruments / kits for testing that have not received approval from the FDA for use in the United States, even if widely used in other countries.

2. Using reagent / instrument combinations that do not have FDA approval. This might mean using reagents from manufacturers different from those of the instrument, and which are not listed by either the instrument or reagent manufacturer as approved for use by either.

3. Deviating from manufacturers' directions for performing the tests.

4. "Off-label use": utilizing the test in a manner not yet approved by the FDA.

   A special note about "Off-label Use" of waived blood glucose monitoring systems:

   Using a waived blood glucose monitoring system (BGMS) to test a patient whose hematocrit or oxygenation level is above or below the range indicated in the manufacturer's instructions would be an example of an "off- label use" of this system. Results of blood glucose testing in this situation may lead to clinical interventions that could cause patient harm. If the patient's hematocrit and oxygenation level are within the manufacturer's stated limits, then performing a glucose test using the waived glucose monitoring system would not be considered off-label testing and the test system would still be considered waived.

(New) Laboratory Developed Tests (LDTs)

In the past, these have also been referred to as "in-house" tests. These are tests that have been developed, evaluated and validated by the laboratory itself. Often, a laboratory will choose to develop and use an LDT because a commercial test is not available to meet their needs. LDTs generally have not been subjected to FDA oversight because these diagnostic tests are never sold to other laboratories or hospitals. Historically, LDTs comprised a relatively small volume of testing intended for use in diagnosing rare diseases or to meet the specific needs of a local patient population.

There can be several reasons why a commercial test has not been developed for a particular analyte or disease of interest. For example, many LDTs are genetic tests developed for rare diseases. These are also diseases affecting only a small subset of the population, thus reducing the incentive for a manufacturer to develop a commercial version because the market for such a product would be small, without a potential decent return on investment.

Even one modified test system will change your laboratory to a testing facility that must meet all applicable CLIA requirements for high-complexity testing

If your laboratory is CLIA waived, and you modify a waived test system, the modified test system must now meet all applicable CLIA requirements for high complexity testing. These include added requirements for Proficiency Testing, the establishment of Performance Specifications, Quality Control, Quality Assessment, and adherence to high complexity personnel qualifications. Laboratories with a CLIA Certificate of Waiver (COW) that are using modified test systems will need to upgrade to a CLIA Certificate of Compliance (COC) or a CLIA Certificate of Accreditation (COA), if they continue to use modified test systems; this includes required biennial on-site inspections.

If your laboratory is a moderate complexity CLIA facility, and you modify a moderate complexity test system, this test system also defaults to the high complexity testing category and will require the modified test system to meet all applicable CLIA requirements for high complexity testing, including the establishment of performance specifications, and adherence to high complexity personnel qualifications. No change in compliance or accreditation certificates would be needed.

High Complexity Testing requirements include:

1. The Establishment of Performance Specifications

A key requirement of the CLIA regulations for all laboratories that modify an FDA-cleared or approved test system is to establish (validate) performance specifications for that test system (i.e., accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range of test results, reference intervals and any other performance characteristic required for test performance).

The FDA requires that modified or lab developed tests provide target values for test results and provide evidence for the expected ranges as well as information on test limitations and other factors that could generate false results.

The validation results include a statement as to whether the method is fit for the intended use. The needs of the customer define the intended use of the method. If all the data quality objectives are met as indicated by the data collected, the method is considered as validated.

Note: State and local jurisdictions vary in how they regulate laboratory testing. Some have requirements governing testing, personnel licensure, or phlebotomy. The person overseeing testing should ensure that all state and local requirements are met. When state, local, and federal requirements are not the same, follow the strictest requirement that applies to your site.

Validation standards set by accreditation organizations may also meet or exceed those set by CLIA, including standards regarding evaluation of lab-developed tests. Participating laboratories must meet these standards and criteria as well.

2. More Stringent Personnel Requirements

The personnel standards for high-complexity laboratories are appropriately more stringent than the requirements for moderate-complexity facilities. There are five positions that must be filled in high-complexity labs:

A. Director;
B. Technical supervisor;
C. General supervisor;
D. Clinical consultant, and
E. Testing personnel.

A significant commitment in resources may be needed to fulfill these requirements if the laboratory is not a high complex facility already.

Detailed CLIA personnel requirements for high complexity testing can be found at http://www.mass.gov/eohhs/docs/dph/clinical-lab/clia-lab-qualifications.pdf

The decision: whether to continue using your modified or laboratory developed test procedure or not?

This requires you to perform a cost / benefit analysis, taking into consideration the following:

Does the modification of your test procedure change the complexity of your laboratory from waived or moderate complexity to high complexity? Is it worth all the attendant CLIA requirements for high complexity testing, including additional types of personnel, higher levels of personnel qualifications, more stringent performance specifications, additional quality control procedures, and even a new a CLIA classification for the laboratory?

If you are already a high complexity laboratory, consider the cost of establishing additional performance specifications, and the need for added personnel who are qualified to perform high complexity tests.

Irwin Z. Rothenberg is a Technical Writer/Quality Advisor for COLA's Educational subsidiary, COLA Resources, Inc. (CRI), a leader in online continuing education for physicians, laboratory personnel, and allied health professionals. CRI offers continuing education through online courses, informational products in both electronic and hard copy form, webinars on cutting-edge technology and regulatory issues, and CRI on-site Symposia for Clinical Laboratories, providing live educational sessions and interactive workshops with leading industry organizations. For more information, visit their website at www.criedu.org or call 1-800-981-9883.

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ASSESSING AND MONITORING COVID-19 PATIENTS.

Urgent care facilities, primary care practices, and other outpatient settings at the front lines of the COVID-19 pandemic need on-site testing solutions to support patient assessment and monitoring. With-patient testing can lead to better healthcare performance by facilitating decisions that can optimize patient outcomes in real time, improving the quality of patient care.

For facilities treating COVID-19 patients, having rapid, accurate diagnostic test results may be useful when assessing or monitoring patients for:

- **C-Reactive Protein (CRP)**
  Levels may be elevated in COVID-19 cases, especially severe cases.[2-15]
- **Liver, Kidney and Cardiac function**
  Elevated levels of the following biomarkers may be indicators of COVID-19 severity:[16-27]
  - Alanine Aminotransferase (ALT)[16,17,20-27]
  - Albumin (ALB)[16,19-22,25-27]
  - Aspartate Aminotransferase (AST)[16,17,19-21,23-26]
  - Creatine Kinase (CK)[16,18,20,22-24]
  - Creatinine (CREAT)[16,22,23,25,27]
  - Total Bilirubin (TBILI)[16,20,25,27]



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ALB, ALP, ALT, AMY, AST, GGT, tBIL, TP

*Calculated

MODERATELY COMPLEX PANELS



BioChemistry Panel Plus
ALB, ALP, ALT, AMY, AST, BUN, Ca, Crea, Glu, GGT, TP, UA, CRP, eGFR*



MetLyte Plus CRP
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, CRP, eGFR*



Hepatic Function Panel
ALB, ALP, ALT, AST, tBIL, dBIL, TP

To learn how the Piccolo Xpress portable diagnostic analyzer can help transform your patient care, contact your Abbott Point of Care Representative or visit www.pointofcare.abbott

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COVID-19 Channel Brochure - US 2994Rev.1 09/20

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PRODUCT FEATURE



SOFIA® 2 FLUORESCENT IMMUNOASSAY ANALYZER AND RAPID DIAGNOSTIC TEST KITS

From Quidel

Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

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This point-of-care (POC) designated test is one of the top-used amongst our customers.

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- Anterior nasal swab specimen collection
- Detects SARS-CoV-2 nucleocapsid protein antigen
- 87.2% sensitivity and 100% specificity

This test is not FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories.

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From CryoConcepts

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1723

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This pen-like device is the perfect choice when low entry costs, portability, and precise delivery are critical to the practice. CryOmega® dispenses nitrous oxide – the coldest portable cryogen and the pinpoint tip allow physicians to effective treat the lesion site without harming healthy tissue.

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1724



1725

CRYOCLEAR®

From CryoConcepts

This is a new pen-like cryo devices that dispenses carbon dioxide which is perfect for superficial lesions such as sun spots, age spots, and shin tags. CryoClear® has enough gas to treat between 20 and 30 lesions depending on the size and type.

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From Siemens Healthineers

Siemens Healthineers DCA Vantage® and CLINITEK Status® family of analyzers provide hemoglobin A1c (HbA1c) and albumin-to-creatinine ratio (ACR) testing at the point of care. Meet quality measures for A1c control and kidney disease check in minutes with CLIA-waived HbA1c testing and ACR[1] ratio. Improve patient experience and overall outcome by providing actionable results in minutes.

1. Moderately complex on the DCA Vantage Analyzer. CLIA-waived on the CLINITEK Status+ Analyzer.

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LAB-ACCURATE RESULTS FOR ACR AND HBA1C

From Abbott

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The CLIA-waived Alere Cholestech LDX™ Analyzer is engineered for confidence, providing accurate, actionable, and readily accessible results that have set the standard in point-of-care lipid profile, cholesterol, and glucose testing. Results are easy to obtain. Fingerstick sampling and a small sample size (40µL) makes results less painful and time consuming.

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Sofia® 2 Fluorescent Immunoassay Analyzer and Rapid Diagnostic Test Kits Sofia 2 takes rapid testing to a new level. Proven lateral-flow technology and advanced fluorescent chemistry are all integrated into this small benchtop analyzer which can be used in any point-of-care setting. Sofia 2 kits are easy to use and adaptable to any healthcare setting. Excellent performance, objectivity, quality control, LIS capabilities, and an expanding test menu make Sofia 2 the perfect solution for the physician's office laboratory.

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OSOM ULTRA PLUS FLU A&B TEST

From Sekisui Diagnostics

Stronger Clinical Performance Takes Lateral Flow Testing To The Next Level. Providing superior rapid results at the point-of-care. Fast, easy, cost effective so you can test and treat in one visit.

- High Performance- Equivalent or exceeding the performance of reader devices, without the need for an instrument
- Results in 10 minutes
- OSOM® Custom Care- Exceptional Support/Training by licensed medical technologists and experienced healthcare professionals
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FLU AND RESPIRATORY



ACUCY INFLUENZA A&B TEST

From Sekisui Diagnostics

The Acucy™ Influenza A&B Test is for the rapid, qualitative detection of influenza A and B viral nucleoprotein antigens from both nasal and nasopharyngeal swabs. Utilizing the Acucy™ Reader in either the point-of-care or laboratory setting, workflow flexibility is achieved with both Read Now and Walk Away features. The combination provides clinicians with standardized and definitive result interpretation.

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HEMATOLOGY ANALYZERS

TURN SMALL PLACES INTO SMART SPACES

From Abbott

With reduced budgets, shrinking laboratory space and staffing challenges, many laboratories need a solution that lets them work smarter with less. The CELL-DYN Emerald 22 AL is a full performance, automated optical 5-part differential analyzer that delivers smarter results for small to midsize clinical laboratories.

- Compact Design
- Walkaway Functionality
- Ease Of Use
- Smart Safety Features

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CELL-DYN EMERALD HEMATOLOGY ANALYZER

From Abbott

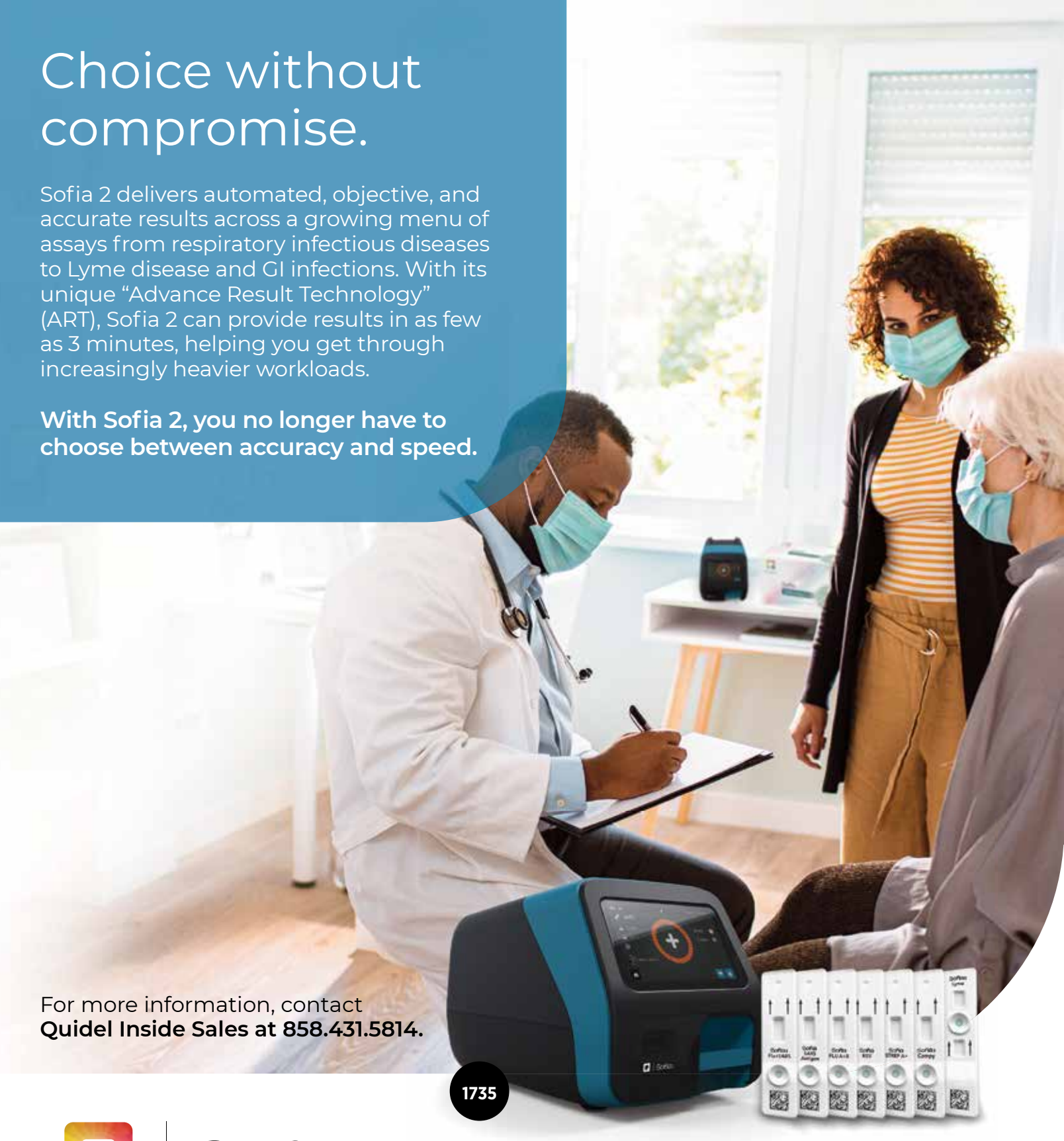
CELL-DYN Emerald is a 3-part differential hematology analyzer that offers high performance in an affordable, compact design that provides reliable and accurate patient results every time. As a smaller operating laboratory, you need a solution that offers reliable results. CELL-DYN Emerald provides results in under 65 seconds. CELL-DYN Emereald's small size, simple touch screen software and reliability offer an easy-to-use, truly compact table/bench top instrument for easy performance in your laboratory.

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Choice without compromise.

Sofia 2 delivers automated, objective, and accurate results across a growing menu of assays from respiratory infectious diseases to Lyme disease and GI infections. With its unique "Advance Result Technology" (ART), Sofia 2 can provide results in as few as 3 minutes, helping you get through increasingly heavier workloads.

With Sofia 2, you no longer have to choose between accuracy and speed.



For more information, contact
Quidel Inside Sales at 858.431.5814.

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RSV | Strep A+ | Lyme | Campylobacter

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AD10102100EN00 (03/22)

HEMATOLOGY ANALYZERS



1736

PENTRA 60 C+ HEMATOLOGY ANALYZER WITH 5-PART DIFFERENTIAL

From HORIBA Medical

Now you can have the same results hospitals and reference labs provide in a small, benchtop analyzer. The Pentra 60 C+ hematology analyzer provides a CBC with 5-part differential result using proprietary technology that ensures an accurate count and differential on the first run. Reduce repeats and reflex to the microscope with Pentra hematology technology.

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MICROS HEMATOLOGY ANALYZER WITH 3-PART DIFFERENTIAL PLUS THE LITEDM

From HORIBA Medical

Is it viral or bacterial? A CBC with 3-part differential can provide the clues to help distinguish between viral and bacterial infections before you decide to treat. The Micros 60 Hematology analyzer provides a CBC with 3-part Diff result in less than 60 seconds using only 10 µL of sample. Connect to the Lite^{DM} Patient Data Management System for an affordable way to consolidate patient results to one report.

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1737

STREP TESTS



1738

OSOM® ULTRA STREP A TEST

From Sekisui Diagnostics

The OSOM® Ultra Strep A test is a color immunochromatographic assay intended for the qualitative detection of Group A Streptococcus antigen directly from throat swab specimens. Shown to be not statistically different than single swab culture. Sensitivity 95.7% and 100% Specificity. Includes two additional test sticks for External QC. CLIA Waived..

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1 Neuro-Cognitive Testing

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- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- **Reimburses using 6 CPT codes, National Average = $750 - $1000 per test**
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing

(can be combined with SUDOMOTOR into 1 full system)

1740

- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- **Reimburses $170/test using 3 CPT codes**
- Provides a 1 page summary up to a full 24 page comprehensive report

3 SudoMotor Testing

1741

(can be combined with ANS into 1 full system)

- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- **Reimburses $130/test (national average)**



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CALQUENCE®
(acalabrutinib) 100 mg capsules

CALQUENCE CONFIDENCE

ELEVATE-RR: THE FIRST PHASE 3 HEAD-TO-HEAD TRIAL OF CALQUENCE VS IBRUTINIB IN R/R CLL[1]

Study Design[2]

A randomized, multicenter, open-label, Phase 3 trial of CALQUENCE vs ibrutinib in patients with relapsed/refractory CLL with the presence of 17p deletion and/or 11q deletion. Patients (N=533) were randomized 1:1 to receive either CALQUENCE 100 mg orally twice daily or ibrutinib 420 mg orally once daily until disease progression or unacceptable toxicity. Primary endpoint was PFS by IRC assessment (non-inferiority; tested after ≈250 events). Secondary endpoints were incidence of any-grade atrial fibrillation, incidence of Grade ≥3 infections, incidence of Richter's transformation, and OS.

SELECT EVENTS OF CLINICAL INTEREST[2]

	CALQUENCE (n=266)		ibrutinib (n=263)	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
CARDIOVASCULAR EVENTS				
Cardiac events	24	9	30	10
Atrial fibrillation*	9	4.9	16	3.8
Ventricular arrhythmias†	0	0	1.1	0.4
Bleeding events	38	3.8	51	4.6
Major bleeding events‡	4.5	3.8	5	4.6
Hypertension§	9	4.1	23	9
OTHER				
Infections‖	78	31	81	30
Interstitial lung disease/pneumonitis	2.6	0.4	7	0.8
Second primary malignancies, excluding non-melanoma skin cancers	9	6	8	5

All grade cardiac arrhythmias of unspecified origin were reported including tachycardia (2.6%), arrhythmia (0;8%), and extrasystoles (0.8%) for CALQUENCE; tachycardia (2.7%), arrhythmia (0.8%), and extrasystoles (0.4%) for ibrutinib.[2]

The most common AEs of any grade (≥20%) in patients receiving CALQUENCE were infections, bleeding, diarrhea, headache, cough, upper respiratory tract infection, neutropenia, pyrexia, anemia, and fatigue.[2]

Median duration of exposure: 38.3 months (range: 0.3-55.9) in the CALQUENCE arm; 35.5 months (range: 0.2-57.7) in the ibrutinib arm.[2]

*Defined as the preferred terms atrial fibrillation and atrial flutter.[2]
†Includes events with preferred terms: ventricular arrhythmia, ventricular extrasystoles, and ventricular fibrillation.[2]
‡Defined as any hemorrhagic event that was serious, Grade ≥3 in severity, or a central nervous system hemorrhage (any-severity grade).[2]
§Defined as the preferred terms of hypertension, blood pressure increased, and blood pressure systolic increased.[2]
‖Most common Grade ≥3 infections were pneumonia (CALQUENCE, 10.5%; ibrutinib, 8.7%), sepsis (CALQUENCE, 1.5%; ibrutinib, 2.7%), and urinary tract infection (CALQUENCE, 1.1%; ibrutinib, 2.3%).[2]

ASCEND: THE FIRST STUDY OF A BTKi VS IdR OR BR IN R/R CLL[3]

Study Design[3,4]

A Phase 3, open-label, randomized, multicenter trial in patients with relapsed/refractory CLL. Patients (N=310) were randomized 1:1 to either receive CALQUENCE monotherapy 100 mg approximately every 12 hours until disease progression or unacceptable toxicity, or investigator's choice of IdR or BR. Primary endpoint at the interim analysis was IRC-assessed PFS. Primary endpoint in the final analysis was investigator-assessed PFS. Select secondary endpoints were ORR, OS, and safety.

EVENTS OF CLINICAL INTEREST[4]

	CALQUENCE (n=154)		IdR (n=118)		BR (n=35)	
	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)	Any Grade (%)	Grade ≥3 (%)
CARDIOVASCULAR EVENTS						
Cardiac events	13	3	8	3	9	9
Atrial fibrillation	5	1	3	1	3	3
Ventricular tachyarrhythmias*	0	0	0	0	0	0
Bleeding	26	2	8	3	6	3
Major bleeding†	2	2	3	3	3	3
Hypertension	3	2	4	1	0	0
OTHER						
Hepatotoxicity‡	5	2	28	22	9	6
Infections	57	15	65	28	49	11

At interim analysis,[5] the most common AEs (≥20%) of any grade in patients receiving CALQUENCE were infection, neutropenia, anemia, thrombocytopenia, lymphocytopenia, and headache.[3]

The median duration of exposure to CALQUENCE was 15.7 months.[3]

*All Grade cardiac arrhythmias of unspecified origin were reported, including arrhythmia (0.7%), bradycardia (0.7%), and tachycardia (0.7%) for CALQUENCE.[4]
†Defined as any serious or grade ≥3 bleeding or central nervous system bleeding of any grade. In the acalabrutinib group, events were gastrointestinal hemorrhage (n=2) and immune thrombocytopenic purpura (n=1); for idelalisib plus rituximab, gastrointestinal hemorrhage, immune thrombocytopenic purpura, and hematuria (n=1 each); and for bendamustine plus rituximab, hemorrhagic anemia and tumor hemorrhage (both in 1 patient).[3]
‡Defined as a select group of hepatic events including hepatic failure, fibrosis, cirrhosis, and other liver damage-related conditions, liver-related investigations, abnormalities, and noninfectious hepatitis.[3]
§Median 16.1-month follow-up.[4]

AEs=adverse events; ALT=alanine aminotransferase; AST=aspartate aminotransferase; BR=bendamustine + rituximab; BTKi=Bruton tyrosine kinase inhibitor; CLL=chronic lymphocytic leukemia; IdR=idelalisib + rituximab; IRC=independent review committee; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; R/R=relapsed/refractory.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

CALQUENCE is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) capsules

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE. Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%). These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jiroveci* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.
Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.
Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

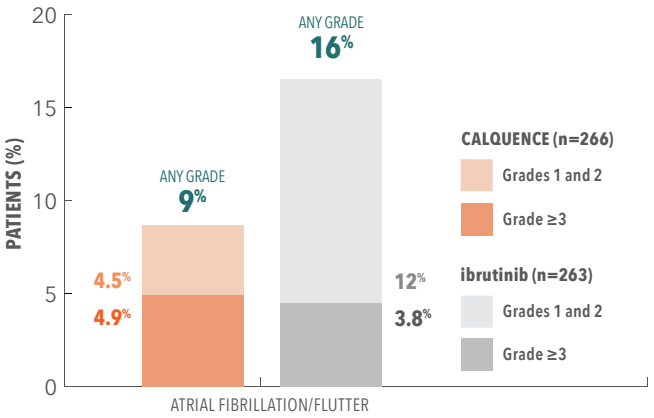
IN RELAPSED/REFRACTORY CLL

LOW RATES OF ATRIAL FIBRILLATION[2,4]

VIEW HEAD-TO-HEAD TRIAL RESULTS

ELEVATE-RR: CALQUENCE VS IBRUTINIB

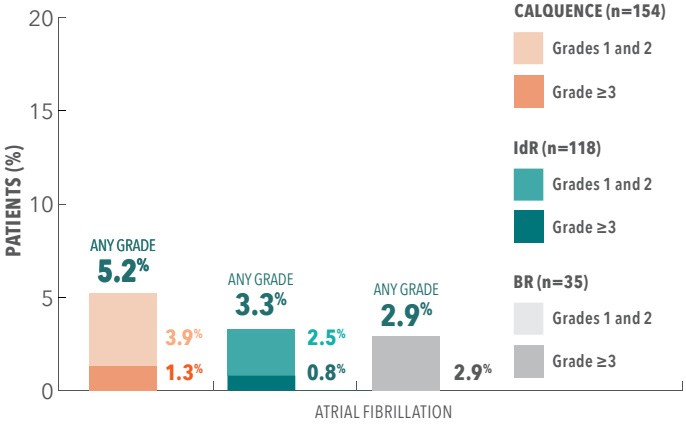
LOW RATES OF ATRIAL FIBRILLATION/FLUTTER ACROSS SEVERITY/GRADES[2]



ASCEND: CALQUENCE VS IdR OR BR

LOW RATES OF ATRIAL FIBRILLATION AT THE INTERIM ANALYSIS*[4]

*The interim analysis had a median follow-up of 16.1 months.



RATES OF NEW ONSET ATRIAL FIBRILLATION/FLUTTER (ANY GRADE) IN ELEVATE-RR IN PATIENTS WITHOUT HISTORY OF ATRIAL FIBRILLATION/FLUTTER[2]

6% (15/243) for CALQUENCE — **15% (37/249) for ibrutinib**

Among patients who experienced atrial fibrillation/flutter events, **0 patients discontinued treatment in the CALQUENCE arm** and 7 (17%) discontinued treatment in the ibrutinib arm[2]

IMPORTANT SAFETY INFORMATION (CONT'D)

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (e.g., palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The most common adverse reactions (≥ 30%) of any grade in patients with CLL were anemia,* neutropenia,* thrombocytopenia,* headache, upper respiratory tract infection, and diarrhea.

*Treatment-emergent decreases (all grades) of hemoglobin, platelets, and neutrophils were based on laboratory measurements and adverse reactions.

In patients with relapsed/refractory CLL exposed to CALQUENCE, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in > 5% of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection. Adverse reactions led to CALQUENCE dose reduction in 3.9% of patients (N=154), dosage interruptions in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and discontinuation in 10% of patients, most frequently due to second primary malignancies followed by infection. Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 1.3% of patients who received CALQUENCE.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration with a strong CYP3A inhibitor. If a strong CYP3A inhibitor will be used short-term, interrupt CALQUENCE.
Moderate CYP3A Inhibitors: When CALQUENCE is co-administered with a moderate CYP3A inhibitor, reduce CALQUENCE dose to 100 mg once daily.
Strong CYP3A Inducers: Avoid co-administration with a strong CYP3A inducer. If a strong CYP3A inducer cannot be avoided, increase the CALQUENCE dose to 200 mg approximately every 12 hours.
Gastric Acid Reducing Agents: If treatment with a gastric acid reducing agent is required, consider using an H2-receptor antagonist or an antacid. Take CALQUENCE 2 hours before taking an H2-receptor antagonist. Separate dosing with an antacid by at least 2 hours. Avoid co-administration with proton pump inhibitors. Due to the long-lasting effect of proton pump inhibitors, separation of doses may not eliminate the interaction with CALQUENCE.

SPECIFIC POPULATIONS

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women of the potential risk to a fetus. Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for at least 1 week following the last dose of CALQUENCE.

It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for at least 2 weeks after the final dose. Avoid administration of CALQUENCE in patients with severe hepatic impairment. Dose modifications are not required for patients with mild or moderate hepatic impairment.

Please see Brief Summary of full Prescribing Information on adjacent pages.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References:
1. Study of Acalabrutinib (ACP-196) Versus Ibrutinib in Previously Treated Subjects With High Risk CLL. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT02477696. Published June 23, 2015. Accessed October 29, 2021. **2.** Byrd JC, Hillmen P, Ghia P, et al. Acalabrutinib versus ibrutinib in previously treated chronic lymphocytic leukemia: results of the first randomized phase III trial. *J Clin Oncol*. Published online July 26, 2021:JCO.21.01210 and supplementary appendix. **3.** CALQUENCE [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2019. **4.** Ghia P, Pluta A, Wach M, et al. ASCEND: phase III, randomized trial of acalabrutinib versus idelalisib plus rituximab or bendamustine plus rituximab in relapsed or refractory chronic lymphocytic leukemia. *J Clin Oncol*. 2020;38(25):2849-2861.

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AstraZeneca

CALQUENCE® (acalabrutinib) 100 mg capsules

CALQUENCE® (acalabrutinib) capsules, for oral use
Initial U.S. Approval: 2017

Brief Summary of Prescribing Information.
For full Prescribing Information consult official package insert.

INDICATIONS AND USAGE

Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
CALQUENCE is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

DOSAGE AND ADMINISTRATION

Recommended Dosage

CALQUENCE as Monotherapy

For patients with CLL or SLL, the recommended dose of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

CALQUENCE in Combination with Obinutuzumab

For patients with previously untreated CLL or SLL, the recommended dose of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity. Start CALQUENCE at Cycle 1 (each cycle is 28 days). Start obinutuzumab at Cycle 2 for a total of 6 cycles and refer to the obinutuzumab prescribing information for recommended dosing. Administer CALQUENCE prior to obinutuzumab when given on the same day.

Advise patients to swallow capsule whole with water. Advise patients not to open, break or chew the capsules. CALQUENCE may be taken with or without food. If a dose of CALQUENCE is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time.

Extra capsules of CALQUENCE should not be taken to make up for a missed dose.

Recommended Dosage for Hepatic Impairment
Avoid administration of CALQUENCE in patients with severe hepatic impairment.

Dose modifications are not required for patients with mild or moderate hepatic impairment *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

Recommended Dosage for Drug Interactions

Dose Modifications for Use with CYP3A Inhibitors or Inducers

These are described in Table 1 *[see Drug Interactions (7) in the full Prescribing Information]*.

Table 1: Recommended Dose Modifications for Use with CYP3A Inhibitors or Inducers

CYP3A	Co-administered Drug	Recommended CALQUENCE use
Inhibition	Strong CYP3A inhibitor	Avoid concomitant use. If these inhibitors will be used short-term (such as anti-infectives for up to seven days), interrupt CALQUENCE.
	Moderate CYP3A inhibitor	100 mg once daily.
Induction	Strong CYP3A inducer	Avoid concomitant use. If these inducers cannot be avoided, increase CALQUENCE dose to 200 mg approximately every 12 hours.

Concomitant Use with Gastric Acid Reducing Agents

Proton Pump Inhibitors: Avoid concomitant use *[see Drug Interactions (7) in the full Prescribing Information]*.

H2-Receptor Antagonists: Take CALQUENCE 2 hours before taking a H2-receptor antagonist *[see Drug Interactions (7) in the full Prescribing Information]*.

Antacids: Separate dosing by at least 2 hours *[see Drug Interactions (7) in the full Prescribing Information]*.

Dose Modifications for Adverse Reactions
Recommended dose modifications of CALQUENCE for Grade 3 or greater adverse reactions are provided in Table 2.

Table 2: Recommended Dose Modifications for Adverse Reactions

Event	Adverse Reaction Occurrence	Dose Modification (Starting dose = 100 mg approximately every 12 hours)
Grade 3 or greater non-hematologic toxicities, Grade 3 thrombocytopenia with bleeding, Grade 4 thrombocytopenia or Grade 4 neutropenia lasting longer than 7 days	First and Second	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at 100 mg approximately every 12 hours.
	Third	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at a reduced frequency of 100 mg once daily.
	Fourth	Discontinue CALQUENCE.

Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE).

Refer to the obinutuzumab prescribing information for management of obinutuzumab toxicities.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Serious and Opportunistic Infections
Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%). These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jiroveci* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage
Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias
Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted *[see Dose Modifications for Adverse Reactions (2.4) in the full Prescribing Information]*.

Second Primary Malignancies
Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter
Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (e.g., palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious and Opportunistic Infections *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hemorrhage *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Cytopenias *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Second Primary Malignancies *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Atrial Fibrillation and Flutter *[see Warnings and Precautions (5.5) in the full Prescribing Information]*

Clinical Trials Experience
As clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data in the Warnings and Precautions reflect exposure to CALQUENCE 100 mg approximately every 12 hours in 1029 patients with hematologic malignancies. Treatment includes CALQUENCE monotherapy in 820 patients in 6 trials, and CALQUENCE with obinutuzumab in 209 patients in 2 trials. Among these recipients of CALQUENCE, 88% were exposed for at least 6 months and 79% were exposed for at least one year. In this pooled safety population, adverse reactions in ≥ 30% of 1029 patients were anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain.

Chronic Lymphocytic Leukemia

The safety data described below reflect exposure to CALQUENCE (100 mg approximately every 12 hours, with or without obinutuzumab) in 511 patients with CLL from two randomized controlled clinical trials *[see Clinical Studies (14.2) in the full Prescribing Information]*.

The most common adverse reactions (≥ 30%) of any grade in patients with CLL were anemia, neutropenia, thrombocytopenia, headache, upper respiratory tract infection, and diarrhea.

ELEVATE-TN

The safety of CALQUENCE plus obinutuzumab (CALQUENCE+G), CALQUENCE monotherapy, and obinutuzumab plus chlorambucil (GClb) was evaluated in a randomized, multicenter, open-label, actively controlled trial in 526 patients with previously untreated CLL *[see Clinical Studies (14.2) in the full Prescribing Information]*.

Patients randomized to the CALQUENCE+G arm were treated with CALQUENCE and obinutuzumab in combination for six cycles, then with CALQUENCE as monotherapy until disease progression or unacceptable toxicity. Patients initiated obinutuzumab on Day 1 of Cycle 2, continuing for a total of 6 cycles. Patient randomized to CALQUENCE monotherapy received CALQUENCE approximately every 12 hours until disease progression or unacceptable toxicity. The trial required age ≥ 65 years of age or 18 to < 65 years of age with a total Cumulative Illness Rating Scale (CIRS) > 6 or creatinine clearance of 30 to 69 mL/min, hepatic transaminases ≤ 3 times upper limit of normal (ULN) and total bilirubin ≤ 1.5 times ULN, and allowed patients to receive antithrombotic agents other than warfarin or equivalent vitamin K antagonists.

During randomized treatment, the median duration of exposure to CALQUENCE in the CALQUENCE+G and CALQUENCE monotherapy arms was 27.7 months (range 0.3 to 40 months), with 95% and 92% and 89% and 86% of patients with at least 6 months and 12 months of exposure, respectively. In the obinutuzumab and chlorambucil arm the median number of cycles was 6 with 84% of patients receiving at least 6 cycles of obinutuzumab, 70% of patients received at least 6 cycles of chlorambucil. Eighty-five percent of patients in the CALQUENCE+G arm received at least 6 cycles of obinutuzumab.

In the CALQUENCE+G and CALQUENCE monotherapy arms, fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% of patients in the CALQUENCE+G arm and 32% in the CALQUENCE monotherapy arm, most often due to events of pneumonia (2.8% to 7%).

In the CALQUENCE+G arm, adverse reactions led to treatment discontinuation in 11% of patients and a dose reduction of CALQUENCE in 7% of patients. In the CALQUENCE monotherapy arm, adverse reactions led to discontinuation in 10% and dose reduction in 4% of patients.

Tables 5 and 6 presents adverse reactions and laboratory abnormalities identified in the ELEVATE-TN trial.

Table 5: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ELEVATE-TN)

Body System Adverse Reaction*	CALQUENCE plus Obinutuzumab N=178		CALQUENCE Monotherapy N=179		Obinutuzumab plus Chlorambucil N=169	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Infections						
Infection†	69	22‡	65	14‡	46	13‡
Upper respiratory tract infection[a]	39	2.8	35	0	17	1.2
Lower respiratory tract infection[b]	24	8	18	4.5	7	1.8
Urinary tract infection	15	1.7	15	2.8	5	0.6
Blood and lymphatic system disorders§						
Neutropenia[c]	53	37	23	13	78	50
Anemia[d]	52	12	53	10	54	14
Thrombocytopenia[e]	51	12	32	3.4	61	16
Lymphocytosis[f]	12	11	16	15	0.6	0.6
Nervous system disorders						
Headache	40	1.1	39	1.1	12	0
Dizziness	20	0	12	0	7	0
Gastrointestinal disorders						
Diarrhea	39	4.5	35	0.6	21	1.8
Nausea	20	0	22	0	31	0
Musculoskeletal and connective tissue disorders						
Musculoskeletal pain[g]	37	2.2	32	1.1	16	2.4
Arthralgia	22	1.1	16	0.6	4.7	1.2
General disorders and administration site conditions						
Fatigue[h]	34	2.2	23	1.1	24	1.2
Skin and subcutaneous tissue disorders						
Bruising[i]	31	0	21	0	5	0
Rash[j]	26	2.2	25	0.6	9	0.6
Vascular disorders						
Hemorrhage[k]	20	1.7	20	1.7	6	0

* Per NCI CTCAE version 4.03
† Includes any adverse reactions involving infection or febrile neutropenia

‡ Includes 3 fatal cases in the CALQUENCE plus obinutuzumab arm, 3 fatal cases in the CALQUENCE monotherapy arm and 1 fatal case in the obinutuzumab plus chlorambucil arm
§ Derived from adverse reaction and laboratory data
[a] Upper respiratory tract infection, nasopharyngitis and sinusitis
[b] Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, and lung infection
[c] Includes neutropenia, neutrophil count decreased, and related laboratory data
[d] Includes anemia, red blood cell count decreased, and related laboratory data
[e] Includes thrombocytopenia, platelet count decreased, and related laboratory data
[f] Includes lymphocytosis, lymphocyte count increased, and related laboratory data
[g] Includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, myalgia, neck pain, pain in extremity and spinal pain
[h] Includes asthenia, fatigue, and lethargy
[i] Includes bruise, contusion, and ecchymosis
[j] Includes rash, dermatitis, and other related terms
[k] Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and epistaxis

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE (CALQUENCE in combination with obinutuzumab and monotherapy) included:

- *Neoplasms:* second primary malignancy (10%), non-melanoma skin cancer (5%)
- *Cardiac disorders:* atrial fibrillation or flutter (3.6%), hypertension (5%)
- *Infection:* herpesvirus infection (6%)

Table 6: Select Non-Hematologic Laboratory Abnormalities (≥ 15% Any Grade), New or Worsening from Baseline in Patients Receiving CALQUENCE (ELEVATE-TN)

Laboratory Abnormality*,[a]	CALQUENCE plus Obinutuzumab N=178		CALQUENCE Monotherapy N=179		Obinutuzumab plus Chlorambucil N=169	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Uric acid increase	29	29	22	22	37	37
ALT increase	30	7	20	1.1	36	6
AST increase	38	5	17	0.6	60	8
Bilirubin increase	13	0.6	15	0.6	11	0.6

*Per NCI CTCAE version 4.03
[a] Excludes electrolytes

Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

ASCEND

The safety of CALQUENCE in patients with relapsed or refractory CLL was evaluated in a randomized, open-label study (ASCEND) *[see Clinical Studies (14.2) in the full Prescribing Information]*. The trial enrolled patients with relapsed or refractory CLL after at least one prior therapy and required hepatic transaminases ≤ 2 times upper limit of normal (ULN), total bilirubin ≤ 1.5 times ULN, and an estimated creatinine clearance ≥ 30 mL/min. The trial excluded patients having an absolute neutrophil count < 500/µL, platelet count < 30,000/µL, prothrombin time or activated partial thromboplastin time > 2 times ULN, significant cardiovascular disease, or a requirement for strong CYP3A inhibitors or inducers. Patients were allowed to receive antithrombotic agents other than warfarin or equivalent vitamin K antagonist.

In ASCEND, 154 patients received CALQUENCE (100 mg approximately every 12 hours until disease progression or unacceptable toxicity), 118 received idelalisib (150 mg approximately every 12 hours until disease progression or unacceptable toxicity) with up to 8 infusions of a rituximab product, and 35 received up to 6 cycles of bendamustine and a rituximab product. The median age overall was 68 years (range: 32-90); 67% were male; 92% were white; and 88% had an ECOG performance status of 0 or 1.

In the CALQUENCE arm, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in > 5% of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection.

In recipients of CALQUENCE, permanent discontinuation due to an adverse reaction occurred in 10% of patients, most frequently due to second primary malignancies followed by infection. Adverse reactions led to dosage interruptions of CALQUENCE in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and dose reduction in 3.9% of patients.

Selected adverse reactions are described in Table 7 and non-hematologic laboratory abnormalities are described in Table 8. These tables reflect exposure to CALQUENCE with median duration of 15.7 months with 94% of patients on treatment for greater than 6 months and 86% of patients on treatment for greater than 12 months. The median duration of exposure to idelalisib was 11.5 months with 72% of patients on treatment for greater than 6 months and 48% of patients on treatment for greater than 12 months. Eighty-three percent of patients completed 6 cycles of bendamustine and rituximab product.

Table 7: Common Adverse Reactions (≥ 15% Any Grade) with CALQUENCE in Patients with CLL (ASCEND)

Body System Adverse Reaction*	CALQUENCE N=154		Idelalisib plus Rituximab Product N=118		Bendamustine plus Rituximab Product N=35	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Infections						
Infection†	56	15‡	65	28‡	49	11
Upper respiratory tract infection[a]	29	1.9	26	3.4	17	2.9
Lower respiratory tract infection[b]	23	6	26	15	14	6
Blood and lymphatic system disorders §						
Neutropenia[c]	48	23	79	53	80	40
Anemia[d]	47	15	45	8	57	17
Thrombocytopenia[e]	33	6	41	13	54	6
Lymphocytosis[f]	26	19	23	18	2.9	2.9
Nervous system disorders						
Headache	22	0.6	6	0	0	0
Gastrointestinal disorders						
Diarrhea[g]	18	1.3	49	25	14	0
Vascular disorders						
Hemorrhage[h]	16	1.3	5	1.7	6	2.9
General disorders						
Fatigue[i]	15	1.9	13	0.8	31	6
Musculoskeletal and connective tissue disorders						
Musculoskeletal pain[j]	15	1.3	15	1.7	2.9	0

*Per NCI CTCAE version 4.03
† Includes any adverse reactions involving infection or febrile neutropenia
‡ Includes 1 fatal case in the CALQUENCE monotherapy arm and 1 fatal case in the Idelalisib plus Rituximab arm
§ Derived from adverse reaction and laboratory data
[a] Upper respiratory tract infection, rhinitis and nasopharyngitis
[b] Includes pneumonia, lower respiratory tract infection, bronchitis, bronchiolitis, tracheitis, and lung infection.
[c] Includes neutropenia, neutrophil count decreased, and related laboratory data
[d] Includes anemia, red blood cell decreased, and related laboratory data
[e] Includes thrombocytopenia, platelet count decreased, and related laboratory data
[f] Includes lymphocytosis, lymphocyte count increased and related laboratory data
[g] Includes colitis, diarrhea, and enterocolitis
[h] Includes hemorrhage, hematoma, hemoptysis, hematuria, menorrhagia, hemarthrosis, and epistaxis
[i] Includes asthenia, fatigue, and lethargy
[j] Includes back pain, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal discomfort, pain in extremity, myalgia, spinal pain and bone pain

Other clinically relevant adverse reactions (all grades incidence < 15%) in recipients of CALQUENCE included:

- *Skin and subcutaneous disorders:* bruising (10%), rash (9%)
- *Neoplasms*: second primary malignancy (12%), non-melanoma skin cancer (6%)
- *Musculoskeletal and connective tissue disorders*: arthralgia (8%)
- *Cardiac disorders*: atrial fibrillation or flutter (5%), hypertension (3.2%)
- *Infection*: herpesvirus infection (4.5%)

Table 8: Select Non-Hematologic Laboratory Abnormalities (≥ 10% Any Grade), New or Worsening from Baseline in Patients Receiving CALQUENCE (ASCEND)

Laboratory Abnormality [a]	CALQUENCE N=154		Idelalisib plus Rituximab Product N=118		Bendamustine plus Rituximab Product N=35	
	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)	All Grades (%)	Grade ≥ 3 (%)
Uric acid increase	15	15	11	11	23	23
ALT increase	15	1.9	59	23	26	2.9
AST increase	13	0.6	48	13	31	2.9
Bilirubin increase	13	1.3	16	1.7	26	11

Per NCI CTCAE version 5
[a] Excludes electrolytes

Increases in creatinine to 1.5 to 3 times ULN occurred in 1.3% of patients who received CALQUENCE.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of acalabrutinib to animals during organogenesis resulted in dystocia in rats and reduced fetal growth in rabbits at maternal exposures (AUC) 2 times exposures in patients at the recommended dose of 100 mg approximately every 12 hours (*see Data*). Advise pregnant women of the potential risk to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In a combined fertility and embryo-fetal development study in female rats, acalabrutinib was administered orally at doses up to 200 mg/kg/day starting 14 days prior to mating through gestational day [GD] 17. No effects on embryo-fetal development and survival were observed. The AUC at 200 mg/kg/day in pregnant rats was approximately 9-times the AUC in patients at the recommended dose of 100 mg approximately every 12 hours. The presence of acalabrutinib and its active metabolite were confirmed in fetal rat plasma.

In an embryo-fetal development study in rabbits, pregnant animals were administered acalabrutinib orally at doses up to 200 mg/kg/day during the period of organogenesis (from GD 6-18). Administration of acalabrutinib at doses ≥ 100 mg/kg/day produced maternal toxicity and 100 mg/kg/day resulted in decreased fetal body weights and delayed skeletal ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 2-times the AUC in patients at 100 mg approximately every 12 hours.

In a pre- and postnatal development study in rats, acalabrutinib was administered orally to pregnant animals during organogenesis, parturition and lactation, at doses of 50, 100, and 150 mg/kg/day. Dystocia (prolonged or difficult labor) and mortality of offspring were observed at doses ≥ 100 mg/kg/day. The AUC at 100 mg/kg/day in pregnant rats was approximately 2-times the AUC in patients at 100 mg approximately every 12 hours. Underdeveloped renal papilla was also observed in F1 generation offspring at 150 mg/kg/day with an AUC approximately 5-times the AUC in patients at 100 mg approximately every 12 hours.

Lactation

Risk Summary

No data are available regarding the presence of acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats. Due to the potential for adverse reactions in a breastfed child from CALQUENCE, advise lactating women not to breast-feed while taking CALQUENCE and for at least 2 weeks after the final dose.

Females and Males of Reproductive Potential

Pregnancy

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy.

Contraception

Females

CALQUENCE may cause embryo-fetal harm and dystocia when administered to pregnant women *[see Use in Specific Populations (8.1) in the full Prescribing Information]*. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for at least 1 week following the last dose of CALQUENCE. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Pediatric Use

The safety and efficacy of CALQUENCE in pediatric patients have not been established.

Geriatric Use

Of the 929 patients with CLL or MCL in clinical trials of CALQUENCE, 68% were 65 years of age or older, and 24% were 75 years of age or older. Among patients 65 years of age or older, 59% had Grade 3 or higher adverse reactions and 39% had serious adverse reactions. Among patients younger than age 65, 45% had Grade 3 or higher adverse reactions and 25% had serious adverse reactions. No clinically relevant differences in efficacy were observed between patients ≥ 65 years and younger.

Hepatic Impairment

Avoid administration of CALQUENCE in patients with severe hepatic impairment. The safety of CALQUENCE has not been evaluated in patients with moderate or severe hepatic impairment *[see Recommended Dosage for Hepatic Impairment (2.2) and Clinical Pharmacology (12.3) in the full Prescribing Information]*.

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STREP TESTS



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TOXICOLOGY

TOXICOLOGY SCREENING SIMPLIFIED ABBOTT'S IMMTOX 270 BENCHTOP ANALYZER NOW WITH 14 ASSAYS CLIA CATEGORIZED AS MODERATE COMPLEXITY

From Abbott

The ImmTox270 benchtop analyzer offers comprehensive toxicology screening solutions for physician offices, treatment centers and independent laboratories.

Broad test menu with over 20 assays to choose from including 14 that are now available as moderately complex.

With complete laboratory solutions from consultation to licensure, and compliance the Abbott Clinical Laboratory Solutions team has you covered.

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TOXICOLOGY URINE DRUG SCREENING REAGENTS

From Abbott

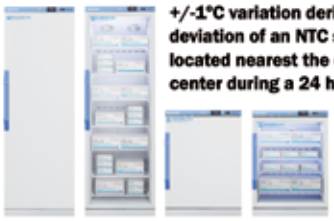
Prescription drug misuse and illicit drug abuse is a growing public health challenge in this country. Building a test profile that covers highly misused drugs has never been so vital. With over 20 relevant assays to choose from Abbott's suite of Immunalysis reagents allows you to easily screen for relevant substances. Our complete line of assays, calibrators, and controls enables you to implement an efficient drug screening program in office.

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VACCINE FREEZERS & REFRIGERATORS

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Solid & Glass Door Refrigerators From 1 to 15 Cu.ft.



+/-1°C variation derived from the maximum deviation of an NTC sensor in a 1 oz. vial located nearest the champer geometric center during a 24 hour test period

1745

Refrigerators & Freezers From 23 to 49 Cu.ft.



Refrigeration designed and purpose-built for pharmacy, medication, and vaccination applications to support meeting CDC/VFC vaccine storage guidelines

Advanced Temperature Control & Durable Performance

- **Intelligent microprocessor digital temperature controller**
- **Adjustable operating control range from +2 to +8°C**
- **Digital display of the min/max temperature in Celsius or Fahrenheit**
- **Password protected control parameters beyond setpoitn**
- **Optimized forced air cooling for excellent stability & uniformity with rapid recovery**
- **Open door and high/low temperature alarms**
- **Factory installed lock conveniently located towards the top of each unit**
- **Adjustable shelving can be spaced in ½" intervals for flexible storage**



Pharma-Vac Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS1PV	1 cu.ft.	21.5"	17.5"	19.5"	White	$936.00
ARG1PV	1 cu.ft.	21.5"	17.5"	20"	Glass	$949.00
ARS3PV	3 cu.ft.	33.75"	18.5"	19"	White	$1,089.00
ARG3PV	3 cu.ft.	33.75"	18.5"	19.5"	Glass	$1,102.00
ARS6PV	6 cu.ft.	32.5"	23.5"	24.5"	White	$1,235.00
ARG6PV	6 cu.ft.	32.5"	23.5"	25"	Glass	$1,266.00
ARS8PV	8 cu.ft.	50"	23.38"	24.5"	White	$1,654.00
ARG8PV	8 cu.ft.	50"	23.38"	25"	Glass	$1,667.00
ARS12PV	12 cu.ft.	61.75"	23.38"	24.5"	White	$2,139.00
ARG12PV	12 cu.ft.	61.75"	23.38"	25"	Glass	$2,152.00
ARS15PV	15 cu.ft.	72"	23.5"	24.5"	White	$2,321.00
ARG15PV	15 cu.ft.	72"	23.5"	25"	Glass	$2,334.00

models with data loggers are available

Pharma-Lab Refrigerators

Accucold	Capacity	Height	Width	Depth	Door	PRICE
ARS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	$2,789.00
ARG23ML	23 cu.ft.	83.75	27.5	31	(1) Glass	$3,114.00
ARS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$4,674.00
ARG49ML	49 cu.ft.	83.75	55.25	31	(2) Glass	$5,031.00

Pharma-Lab Freezers

Accucold	Capacity	Height	Width	Depth	Door	PRICE
AFS23ML	23 cu.ft.	83.75	27.5	31	(1) Stainless	$3,205.00
AFS49ML	49 cu.ft.	83.75	55.25	31	(2) Stainless	$5,194.00

Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1 Estimate the maximum number of doses of publicly-provided vaccine and privately purchased vaccine that will be in your refrigerator.

Refrigerator: Add the number of doses on hand (current inventory) from your last order form.

Public Vaccine _____

Private Vaccine + _____

Total doses = _____

Multiply (max inventory) x 1.25

Maximum doses = _____

2 Match your maximum doses with the minimum cubic feet needed to safely store your vaccine

Max. Doses	Minimum Cubic Ft.
2,000+ doses	may need more than one refrigerator
1000-2000	40 cu.ft
900-1000	36 cu.ft
801-900	21-23 cu.ft
701-800	17-19.5 cu.ft
400-700	11-16.7 cu.ft
100-399	4.9-6.1 cu.ft

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PRODUCT FEATURE



OSOM® BVBLUE®

From Sekisui Diagnostics

The OSOM® BVBLUE® detects elevated vaginal fluid sialidase activity, an enzyme produced by bacterial pathogens associated with bacterial vaginosis including Gardnerella, Bacteroides, Prevotella and Mobiluncus. OSOM® BVBLUE® is more sensitive than Amsel criteria providing physicians with a more accurate diagnosis to treat and minimize serious health consequences such as early spontaneous preterm births and miscarriage.

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OSOM® TRICHOMONAS RAPID TEST

From Sekisui Diagnostics

The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of Trichomonas vaginalis antigens from vaginal swabs or from the saline solution. The OSOM® Trichomonas Rapid Test is a CLIA-waived rapid test available today. OSOM® Trichomonas is more sensitive than wet mount due to the assay being able to detect viable and non-viable organisms which offers significant benefits to the patient and clinician alike.

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ULTRA HCG COMBO TEST

From Sekisui Diagnostics

The OSOM® Ultra hCG Combo test is a simple immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early confirmation of pregnancy. Internal studies have confirmed that the OSOM® Ultra hCG Combo test does not have a false negative result from hCG variants providing physicians with a higher level of confidence.

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- remote diagnostics

ENVOY 500+

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- 10-40 patients per day

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Selectra Pro S

Compact

- 10-15 patients per day

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LEGITIMATE QUESTION: IS IT POSSIBLE TO FIND TRUST-WORTHY FINANCIAL ADVICE?!

Reasons to connect beyond your cousin's college roommate-turned-financial planner about your financial future

BY SCRUBMONEY™ CO-FOUNDERS



It seems you can turn anywhere these days and you'll get financial advice. Look in any direction and you're probably hit with an advertisement, a quick tip, a savvy money narrative to digest, or perhaps even an enthusiastic stranger who swears they'll grow your wealth.

Meanwhile, your mind lingers with questions involving your personal finances that remain unresolved: "Who can I go to for advice?" "Who can I trust for help?" "What financial services address my most urgent needs?"

Certainly, there are many simple steps you can take to set yourself up for a successful financial path. If you're on top of your monthly budget and aware of your incoming and outgoing money flows, you're in better shape than many physicians. With limited time to dedicate to personal financial planning, this is about as far as most of us get. The good news is there is expert and experienced help available — the real challenge may be knowing what you're looking for and how to ask for guidance.

Let's assume you've got a pretty good idea of where you're at financially, meaning you possess a general idea of how much debt you've accumulated to this stage of your career and are bringing home enough income to make ends meet. However, you're looking to avoid financial mistakes, save money more efficiently, invest money and chart a healthy course for the years ahead. It may be time to find a financial planner and access other financial professionals.

Our research shows that many physicians turn to existing relationships when seeking professional financial support. Referrals often come from family members, fellow residents and colleagues, neighbors, and friends. In most cases, this is how financial professionals are introduced to early-career physicians and attendings. Alternatively, physicians know that having a white coat almost immediately attracts financial advisory service professionals — haven't we all been approached, often repeatedly? Some of us are fortunate to find prudent, qualified professionals by these methods. Others aren't so lucky, and sadly feel preyed upon.

For those still looking for financial planning and other specific financial advisory services, we'll lay out some considerations which we hope are helpful. Before diving deeper into specific services, let's look at some typical services needed at various career stages in medicine.

If you're a resident, you'll probably be best served by advisors that can assist with the following: debt repayment strategies (student loans and consumer debts), budgeting and saving prioritization, insurance services (disability and life), tax and estate planning services.

For attending physicians, the previous services remain applicable with additional recommendations for retirement planning, investment management and educational savings for children. As your career progresses nearer retirement, it's certainly advisable to seek financial advice involving re-



tirement income, long-term care planning, and post-career specific financial services.

As medical professionals, we know the value of expertise and specialization. We can similarly use this framework when seeking a financial professional. When searching for an advisor who can look holistically at your (or you and your family's) circumstances, find out how experienced they are at working with physicians. Don't hesitate to ask them for their track-record with healthcare professionals, how they think through some of the financial situations facing medical professionals, such as sizable educational debt and the need for disability insurance. Furthermore, find out if they (along with their firm) provide a full suite of services (planning, tax, insurance, etc.) or if they specialize in one area primarily. Some physicians may prefer a one-stop shop, while others feel confident in having various professionals focused on fewer aspects of finance working together toward a healthy financial future.

If you're encouraged that a prospective financial professional is competent (i.e. experienced) working with physicians and physician families, here are some additional determining factors to consider:

Compensation model: Know how your agent/ advisor is paid for their services.

- We suggest aiming to find a **Fee-Only** advising arrangement, particularly for planning services. The National Association of Personal Financial Advisors takes the position that the Fee-Only method of compensation is the most transparent and objective method available. This model minimizes conflicts and ensures that your financial planner acts as a fiduciary. Fee-Only planners are compensated directly by their clients for advice, plan implementation and for the ongoing management of assets. Fee-only financial advisors may be paid hourly, as a retainer, as a percentage of assets under management, or as a flat fee, depending upon the planner you choose.

- Additional compensation models include **fee-based** (set fee for the client, additionally an agent may receive compensation from other sources, such as a commission for sale of the financial product) and commission-based (agent receives compensation from products sold to client). *One note on the insurance services: you're likely to encounter **commission-based** models in this area. Given this commonly used compensation structure in this industry, we suggest an emphasis on finding proper coverages and quality agents over a determination based solely on an agent's compensation model. More on this below.

One easy way to check for transparency is to find out if an agent is always a fiduciary. In other words, is the advisor obligated to do what is always in the client's best interest? You may be surprised to learn that even fee-based advisors, in some cases, may alternate between the suitability standard (their recommendations only need to be suitable for a client's situation) and the fiduciary standard.

Tax strategies: I need a tax strategy?! The answer is probably yes.

Unless you finished medical school while earning your CPA on the side (highly improbable) or have a personal accountant and tax preparer as your partner, you'll probably need help here. Similar to finding a financial planner, make sure you find an agent experienced with physician personal finances. The reasons for a tax strategy and consulting with a capable, licensed tax advisor are underscored here:

- Tax laws, both at federal and state levels, are ever evolving.

- A plan which considers deductions and capital gains not only for this tax-year but also subsequent tax years will save you money.

- If your household has multiple income sources, certainly you'll need a tax plan with a comprehensive approach, and an agent to advise you through the filing process.

Insurance services: Why choose an Independent Advisor?

An important component of a physician's financial health and financial security will be insurance services, and we strongly urge you to consider an independent advisor when seeking help in this area. The marketplace for insurance policies is wide and an independent agent is best suited to shop the offerings of various companies on your behalf. An independent advisor can walk you through the nuances of policy language, help with determining sound coverages personal to your needs, and highlight key factors for choosing the best company to work with (age, gender, specialty, benefits, etc.). Moreover, an independent agent will not have loyalties to any specific company nor any economic ties to a specific insurer.

If finding trustworthy and competent financial advisors seems bewildering, know that you are not alone. If relationships nearest you (family, friends, colleagues) make introductions to qualified financial professionals, count your blessings! And if you're still wondering how to get this kind of help and not turn prey to rent-seeking financial resources, we hope this article will focus your efforts toward finding fiduciary and fee-only service providers with a focus on transparent client relationships.

This article is authored by co-founders of ScrubMoney, a physician-created and physician-focused mobile app aimed to make sure every physician in the US healthcare system has a strong financial plan so they can better focus on healing their patients and living their lives.

Let’s play a game.

If you can’t answer the following question off the top of your head, you get to download our free physician personal finance education app.

> Say you have 1.5% fees for one of your retirement investments. How many fewer years will your nest egg last than if it was a .1% fee?

We’re offering free foundational personal finance education to physicians because we know that this is part of what it will take to help reduce burnout and help doctors live the lives we want to while taking great care of our patients. And over the course of its lifetime, you’ll lose 10 years’ worth of investing to a 1.5% fee.

And while many physicians already know that, there’s always the issue that **we don’t know what we don’t know**. Beef up your basic physician personal finance knowledge today.

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