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Navigating the shift to omnichannel marketing

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Pharmaceutical and biotechnology companies are shifting from multichannel to omnichannel marketing with a modular content approach to drive better customer experience. The industry is in the early to middle stages of formalizing roadmaps, establishing infrastructure, and performing pilots that will serve as the foundation for fully operationalizing and scaling the transformation. This article discusses omnichannel and modular content, their impacts on regulatory and promotional review, and considerations for preparing review organizations for the change.

Keywords – modular content, personalization, promotional review

Introduction

Many pharmaceutical and biotech companies are preparing to transition to an omnichannel marketing approach for their promotional materials and are being challenged by management to implement the systems, processes, and personnel changes needed to support this flexible and personalized approach to marketing. The issue is that the term *omnichannel* is often misunderstood and, as such, is causing confusion.

While the term may mean different things to different people, *omnichannel* is generally used as a catchall to describe a customer-centric approach that uses data to create and deliver personalized promotional and nonpromotional communications in a seamless experience across channels, thereby facilitating better and faster treatment decisions that contribute to better patient outcomes.

To make that vision a reality – and realize the benefits of an omnichannel strategy while also remaining fully compliant – not only will there be changes to technology and content creation, but companies will also need to fully integrate promotional review teams (PRTs) into the process of preparing for omnichannel

marketing. Innovation creates change, and change is hard. But the foundation of change is understanding, and this article hopes to clarify what omnichannel means to promotional reviewers and elucidate some of the process changes necessary for a smoother transition.

Distinguishing features

To best understand how this advanced marketing technique impacts the medical, legal, and regulatory professionals who compose PRTs, it is helpful to examine how the approach differs from traditional ways of working.

Companies generally have taken a product-centric multichannel approach to marketing. This approach entails repeatedly delivering the same content to all customers (or a group of customers) across channels to generate a desired customer engagement.

In contrast, omnichannel marketing takes a customer-centric approach. Leveraging a stack of advanced technologies and tools, companies deliver personalized content to each individual customer, in their preferred channel, based on their prior interactions, to fulfill that customer's preferred experience. While omnichannel marketing operations are composed of many variables, three features distinguish it from its multichannel predecessor, as shown in the accompanying **Table**.

Data

In omnichannel marketing, a centralized data infrastructure integrates data such as professional demographics, sales, prescriptions, promotional history, and marketing interactions from many sources to provide a unified, or 360-degree view, of the individual customer. That unified customer view fuels a next-best-action predictive model that recommends channels, messaging, content, and so on, based on that customer's needs and preferences. This is sometimes referred to as data-driven orchestration.

Table. Differences between multichannel and omnichannel marketing

Feature	Type of marketing	
	Multichannel	Omnichannel
Data	Data stored in silos and managed separately	Data integrated through a centralized infrastructure providing a unified view of the customer
Channels	Unconnected and operate independently	Connected in real time and work together seamlessly
Messaging and content	Static and repetitive across channels	Personalized; dynamic and adaptive to individual customer behavior

Source: Hale Advisors

The readiness of today's pharmaceutical and biotechnology companies to create a unified customer view and shape marketing strategies accordingly depends on their ability to continuously capture or acquire and integrate data; their acquisition of tools and the competency to perform advanced data analytics; and their ability to connect this data with content authoring, customer relationship management (CRM), marketing automation, digital asset management, promotional review, and other systems.

Channels

In omnichannel marketing, engagement in any channel builds on prior interactions, messages, behavior, and learning from all touchpoints, such that the customer's experience is continuous. Unlike the multichannel marketing experience, customers do not bear the burden of providing context back to the company as they move from one channel to the next, because the system is always capturing and responding to their behavior.

Pharmaceutical and biotechnology companies have been experimenting with or piloting the omnichannel technique in a few specific channels where successful execution of relevant content is most readily achievable:

- Rep-triggered emails (RTE)
- Banner advertising
- Responsive search
- Personalized websites

Messaging and content

Every aspect of omnichannel marketing – from channel to message to content and more – is personalized to the unique, individual customer. While pharmaceutical and biotechnology companies have long been segmenting content to different patient populations and healthcare professional (HCP) specialties, the omnichannel strategy refines this approach by using individual-level data and connected channels to vastly improve personal relevance and experience. The content that is served to the individual is variable, depending on the data and channel, requiring marketers to develop this content at the situation level instead of by channel. One approach to this personalization is the use of modular content, which will be discussed later in this article.

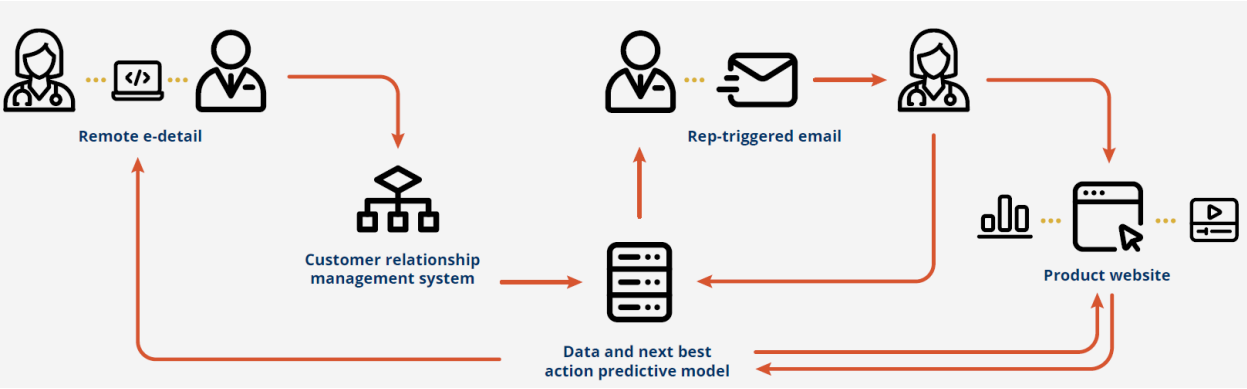
To effectively generate variable content personalized to a unique individual, the industry will need to do something it has never done before: develop standardized content that can be effectively reused across channels. Up to this point, content has been approved for use in a specific channel, and it has been designed only for that physical or digital space. This is a tremendous change for marketers and agencies developing the content, and it is unclear if they will be comfortable creating content that is standardized in this manner.

An example of omnichannel marketing

To illustrate, imagine that a sales representative has a video conference with a low-prescribing HCP and shares digitized product information through an electronic detail or "e-detail" (**Figure 1**). The sales representative learns that the HCP wants to better understand the product's mechanism of action (MoA) and efficacy. Following the face-to-face interaction, the rep updates the CRM system. Based on this trigger event combined with other customer data, the pharmaceutical company's next-best-action engine recommends that field sales deliver an email with additional information about the product's MoA and efficacy. By choosing from the RTE's menu of preapproved content modules, and based on the HCP's profile and needs, the rep customizes the messaging and content and provides links to a website for further information. The HCP goes to the website and searches for safety data. The website then serves additional clinical data and a video of a key opinion leader presenting the safety data, based on previously gathered insights. Nonresponse or data from all these interactions is continuously captured and added to the HCP's profile to inform future engagement and personalization.

Like many marketing innovations, omnichannel marketing originated outside of life sciences in a less regulated industry – retail – and has since been adopted by a wide range of industries, from telecom to financial services. Although the life sciences industry is in a relatively early stage of omnichannel maturity, there is some evidence of a positive commercial impact. A 2022 report noted that early omnichannel adopters observed increases of 5%-10% in revenue, 10%-20% in marketing efficiencies and cost savings, 3%-5% in number of prescribers, and 5%-10% in HCP satisfaction. These improvements are driven by the differentiated insights enabled by advanced analytics that help guide commercial activities: examples include the creation of personalized messages and channels for individual HCPs, and the allocation of resources for greatest impact.[1]

Figure 1. Data-driven orchestration of omnichannel marketing



Source: Hale Advisors

Clearly, there is some indication that making this change could drive business results. That is why, across the industry, companies are developing business cases, making requisite technology, process, and people investments, performing pilots, and forming omnichannel centers of excellence (**Figure 2**).

Optimally, this transformation work would include cross-functional collaboration with digital governance boards and regulatory leadership to ensure that planning for and operationalizing the change to omnichannel marketing proactively accounts for promotional review requirements. One of omnichannel's most significant impacts to promotional review is workflow modifications for the review of content to be used in a modular capacity.

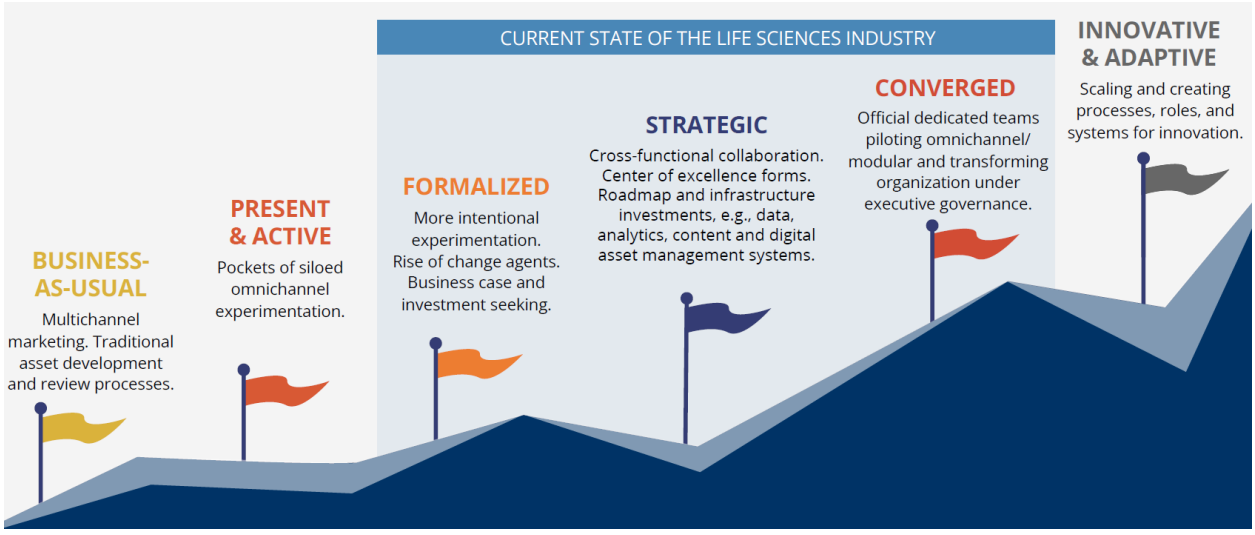
Modular approach to content personalization

Traditionally, pharmaceutical companies have originated advertising and promotional assets from scratch for each new campaign. If a campaign calls for a series of five banner advertisements for each of three HCP segments or personas, marketing designs and writes 15 advertisements or advertisement versions along with corresponding website landing pages and submits each one for promotional review.

Today, the same integrated data and technology innovations that are enabling omnichannel marketing are also allowing companies to supplant that traditional approach with the new practice of modular content.

Modular content refers to blocks of content – modules – that can be assembled in various mix-and-match-style combinations (variable based on data) to create personalized assets for readers and users in any channel. The modular approach

Figure 2. Omnichannel transformation in the life sciences industry during 2023



Source: Hale Advisors. Credit: Altimeter, a Prophet Company. Adapted from 'The Six Stages of Digital Transformation.' CC BY-NC-SA 3.0 DEED. https://creativecommons.org/licenses/by-nc-sa/3.0/us/# [2]

aims to reduce staff hours and cycle time for asset creation and approval, increase consistency and accuracy, and, most importantly, deliver the most relevant content to individual customers no matter the channel.

To achieve this possibility in life sciences, PRTs will need to collaborate with brand and marketing stakeholders to develop and preapprove the following:

- **A core claims library –** Some content management platforms designed for life sciences include a claims library, which is a centralized repository for storing, organizing, and accessing claims-related information. Managed by a dedicated claims librarian, the core claims library is a central enabler of the modular content process. Working from a core claims document or core visual aid, brands and reviewers populate the library with claims and their mandatory linked references, which can be used to create modules. The claims are tagged with keywords that connect a claim to new content automatically (auto claims). This automation can significantly streamline the content development, review, and approval process and provide greater confidence that content is compliant, reducing the risk of producing misleading messaging.

- **The modules –** Each module is composed of distinct but related components, such as product claims text, references text, graphics, images, and videos, that must be approved to operate together as an unbreakable unit. Notably, promotional claims require references, and data points must support studies, which need to travel with the modules. Modules are documented for submission to the US Food and Drug Administration's Office of Prescription Drug Promotion (OPDP) in a content matrix by type.

- **Business rules –** Business rules draw on precedent to govern and specify the use of claims, components within modules, and modules in combination. These rules provide stakeholders with clear definitions of relationships between these content elements and how they are permitted to appear within the template under various circumstances. For example, the rules establish which references must appear with each claim, how components within a module must be presented, which modules must precede or follow each other, and which modules must never appear together to prevent creating misleading claims. It is critical that brand and review teams co-create the business rules to cement the foundation of trust that enables modular execution.

- **Channel templates –** Since the goal of modular content is to repurpose content across channels, layout templates for each channel or asset type provide a roadmap for how the content will appear. A

representative template is also required for submission to the OPDP, though it is not required to show every permutation of modules within the template. Technology is evolving to allow reviewers to see how content would work together in these templates based on the business rules.

With these pieces in place and stored on a digital asset management platform, a marketer, sales rep, or artificial intelligence tool can assemble an asset by selecting a preapproved channel or asset template and populating it with a preapproved combination of preapproved modules, using business rules as a guide.

A life sciences cloud-based software company recently reported that "based on early indicators, a modular content approach is helping one customer reduce time to market by more than 50%. This stems from an increase in content reuse by 40% and an overall decrease in approval times by 30%. Another company is achieving 75% of approvals in a single review cycle, cutting costs by 19%."[3]

In addition to these efficiencies and the increase in asset relevance, the industry also anticipates this approach will reduce regulatory risk because claims and references are already contained within the preapproved modules. While this is surely a benefit, it is also true that modular content will impact the promotional review process in ways that present new challenges.

Impacts on the promotional review process

In a world in which assets are assembled from modules, the ultimate vision for life sciences is that promotional reviewers would review and approve content in module form only, rather than repeatedly reviewing and approving that same content in every asset that is subsequently assembled. In this scenario, reviewers would rely on a content matrix of possible options and a representative sample asset to understand how the content modules would relate in the template. Applying business rules would ensure that the assembled content does not confer unintended meaning. After their approval of these modules, PRT would not review any assets subsequently assembled from the modules. This process would be a fundamental departure from the traditional promotional review workflow, and it has proven to be a massive mindset change and executional challenge for review teams.

As such, the current reality falls somewhere between the old and the new: some pharmaceutical companies that are piloting modular content are reviewing and approving both the modules and the subsequently assembled assets. In this case, submitters annotate the assembled assets to indicate content that was previously approved in module form and submit them to regulatory for a "light" functional review to confirm the modules work together compliantly in the template according to the content matrix.

Although speed to market is often presented as a benefit of modular content and an omnichannel approach, this second functional review would create additional reviewer responsibilities and increase the volume of assets moving through the review process, all of which would increase PRT effort. Companies will need to evaluate and modify their promotional review workflow to manage these changes with efficiency and strive for the one-review goal.

To help create confidence in content developed from modules, it is critical to have clear internal company guidelines that govern how to activate marketing in compliance with regulations in each channel. Guidelines are typically established through a cross-functional governance board and consider factors such as content requirements, space limitations, whether a product has a boxed warning, and whether materials are branded or unbranded. The guidelines then define the requirements for activation in each channel (such as email, website, and social media) accordingly. Partnered with the channel templates, governance and guidelines help provide reviewers with critical foresight about the relationship between modules as they are placed in different channels.

Handling claims updates

Another key consideration in creating this standardized modular content is the impact of revisions, which are inevitable as new studies and marketplace changes affect the claims statements over time. Effective claims updates require teams to establish clear protocols and processes for updating the impacted claims and module libraries, informing stakeholders, and retiring old modules and assets. With these protocols and processes in place, brands can readily amend and submit the affected content modules for promotional review and approval. Upon approval, marketers can replace the affected module in active or in-use assets without requiring a traditional promotional review.

This will require greater confidence from promotional reviewers that marketers will consistently implement the updates, reducing the need for further core reviews of the materials in their final form and opening the door for tiered reviews. Marketers and agency partners could help bridge the knowledge and comfort gap by developing a deeper understanding of claims requirements, thereby casting reviewers in a more advisory capacity for marketers instead of functioning as gatekeepers for the information.

Using Form FDA 2253 for submitting modular content

The OPDP recognizes that omnichannel marketing and modular content innovations are new to the life sciences industry and its stakeholders, and its electronic common technical document (eCTD) page contains all resources and reference materials produced by the OPDP in support of the OPDP Electronic Submissions Guidance.[4] The OPDP encourages submitters to contact its eCTD mailbox with questions regarding variable content and modular content submissions on Form FDA 2253. (Form FDA 2253 is a transmittal form that life

sciences companies must complete to accompany all advertising and promotions submissions to the FDA. The form provides the FDA with the information they need to review the advertising or promotion.)

At the time of this writing, the OPDP accepts Form FDA 2253 submission of variable content modules with a content matrix, business rules, channel or asset templates, and an example of an assembled asset. This submission package is permitted to contain one single channel per submission.

In the event that a postmarket promotional piece is called to the OPDP's attention, it is critical that the OPDP has a historical record of submission for easy reference. This poses a challenge for assets that were submitted as variable content modules instead of as assembled assets. To solve this issue, some companies are establishing a series of unique codes that can be assigned to the possible content permutations generated from a content matrix and are including those codes in the 2253 submission. As each asset is generated, one of those unique codes is assigned to appear on the promotional piece. This enables the OPDP to track the promotion to a submission, which facilitates their review and mitigates the risk of the submitter receiving a Failure to Submit Under Form FDA 2253 violation notice.

Privacy considerations

In our ever-evolving digital landscape, privacy around our online behaviors and interactions has become a priority. However, to create a personalized omnichannel experience, marketers need to gather data on the habits of customers and how they interact with communications. Examples of this data include field rep interactions with physicians, which are logged in a CRM system; website and digital advertising actions, such as registering for an email or clicking through banner advertisements; and search engine engagements, such as keyword searches that generate click-throughs to websites. This data influences how content modules are assembled for subsequent messaging, such as RTEs or banner advertisements appearing on websites or in social media.

From a regulatory perspective, privacy is a key concern in the data-gathering process, both for the data gathered directly and for the information provided by third-party sites where companies advertise. Data and privacy protection legislation, such as the EU General Data Protection Regulation (EU GDPR),[5] has transformed the way in which companies collect and process data obtained from consumers. As a result, it is essential for companies to have a robust data governance framework in place.

Data governance includes written policies that outline compliance measures taken to abide by data privacy regulations and how those measures are implemented throughout the organization. Companies can ensure compliance by starting with an audit of data to understand where it is coming from and how

it is collected, processed, and stored. Additional points to clarify would be whether the company has a legal and lawful reason for collecting the data, and if they have notified customers that they are collecting the data.

Once the company understands the basis of their data, a review of existing policies is necessary to ensure those policies are up to date with regulations. Typically, companies dedicate team members who are responsible solely for monitoring activities to ensure policy adherence and implementation. Quarterly and annual assessments can reduce risk and ensure appropriate safeguards are in place to enable interactions between healthcare and pharmaceutical companies, healthcare professionals, pharmacists, and patients.

How promotional review teams can prepare

From a scale, budget, or infrastructure perspective, some companies may feel unready to invest in the systems or talent required for omnichannel marketing and a modular content approach. However, just as moving to electronic submissions improved the review process well over a decade ago, the opportunity to innovate existing content development and review processes can benefit companies of all sizes right now. To this end, there are two key initiatives PRTs can undertake for each brand in collaboration with their brand and marketing partners:

- **Claims library –** Catalog the claims and references that form the basis of promotional communications. Whether using a content management platform or relying on traditional documentation methods for the library, PRTs can play a leadership role in centralizing and organizing claims to enable marketers to more readily map new content to those claims. The library will provide history, ensure accuracy and consistency, simplify compliance, improve future evolution of claims, and, ultimately, prepare the organization for a shift to variable content.

- **Content components repository –** Extract the smallest distinct content components (text, graphics, images, videos, etc.) from existing approved assets to document, evaluate, catalog, and store discretely. This channel-agnostic approach to reviewing content is one of the largest shifts from the current way of working for marketers, agency partners, and reviewers, but building proficiency will pave the way for truly modular content assembly. It will set the stage for repurposing content more effectively across channels, and it will better protect companies against unsupported claims.

Conclusion

Omnichannel marketing shows promise for increasing efficiencies and providing more personalized customer experiences. However, fully realizing its potential will require significant changes to existing processes, such as promotional

review. Pharmaceutical companies are still in the early stages of adoption but making progress through pilots and centers of excellence. Modular content in particular presents opportunities to streamline asset creation while reusing preapproved materials. The resulting speed of creation, approval, and delivery to market would achieve a significant goal for marketers and their agency partners.

However, modular content also introduces new complexities for promotional review, as content can be assembled in many permutations. Clear guidelines, templates, and tiered functional review of composed assets will help address potential challenges, as will continued collaboration between marketing and regulatory teams. Privacy and data governance must also be strengthened to ensure compliance with regulations such as the EU GDPR. If implemented carefully, with the impacts on promotional review accounted for, omnichannel marketing and modular content could deliver faster approvals, increased relevance, and stronger results. The transformation will take time as companies learn through experience and continue adapting their approaches.

There is a clear benefit to improving workflows, making better use of technology solutions, and reducing the number of reviews. In addition, shifting some of the responsibility to marketers for ensuring that claims are supported and accurate could benefit already overtaxed review departments. Standardizing content for reuse across channels may reduce some of marketing's creativity, but it will also narrow the volume of content for review. And ultimately, these changes can be seen as an opportunity for the industry to improve the promotional review process through claims libraries and auto claims linking even if companies do not move to a full omnichannel approach right now.

Abbreviations

CRM, customer relationship management; **eCTD,** electronic common technical document; **EU GDPR,** EU General Data Protection Regulation; **HCP,** healthcare professional; **MoA,** mechanism of action; **OPDP,** Office of Prescription Drug Promotion; **PRT,** promotional review team; **RTE,** rep-triggered email

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