

A CASE FOR CHANGE IN PATIENT CARE

# THE MULTIPLE MYELOMA CALL-TO-ACTION

## EXECUTIVE SUMMARY

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Globally, many stakeholders commit considerable effort towards improving patient outcomes and experience in multiple myeloma. Multiple initiatives have added substantial value to the myeloma landscape; however, no single collaborative approach that targets the most critical unmet needs in multiple myeloma care exists today.

Johnson & Johnson is committed to changing the course of multiple myeloma. This Call-to-Action has been developed to outline high-priority unmet needs and recommended areas of focus for the global multiple myeloma community, as identified by the Global Multiple Myeloma Collaboration Council.

Through addressing the most prominent unmet needs to advance patient care, outcomes, and experience, the goal is to accelerate progress towards cure for people living with multiple myeloma.<sup>1\*</sup>

\*“Cure” in this document is defined as minimum of 5 years disease-free from date of documented minimal residual disease (MRD) negativity at a sensitivity level of  $10^{-6}$ .<sup>1</sup>

# Introducing the Global Multiple Myeloma Collaboration Council

Johnson & Johnson established the Global Multiple Myeloma Collaboration Council to gather expert perspectives and insights. Members of the Collaboration Council represent a wide range of geographies and disciplines, across 10 countries and 5 continents.

Chaired by Faith Davies, Professor of Medicine at New York University (NYU), the Collaboration Council brings together patient advocates, clinical leaders, researchers, and policy experts, to identify high-priority unmet needs in multiple myeloma care and recommend calls-to-action for the global community.

*Opinions of Collaboration Council members are included throughout this document to provide additional context and perspectives on referenced data.*



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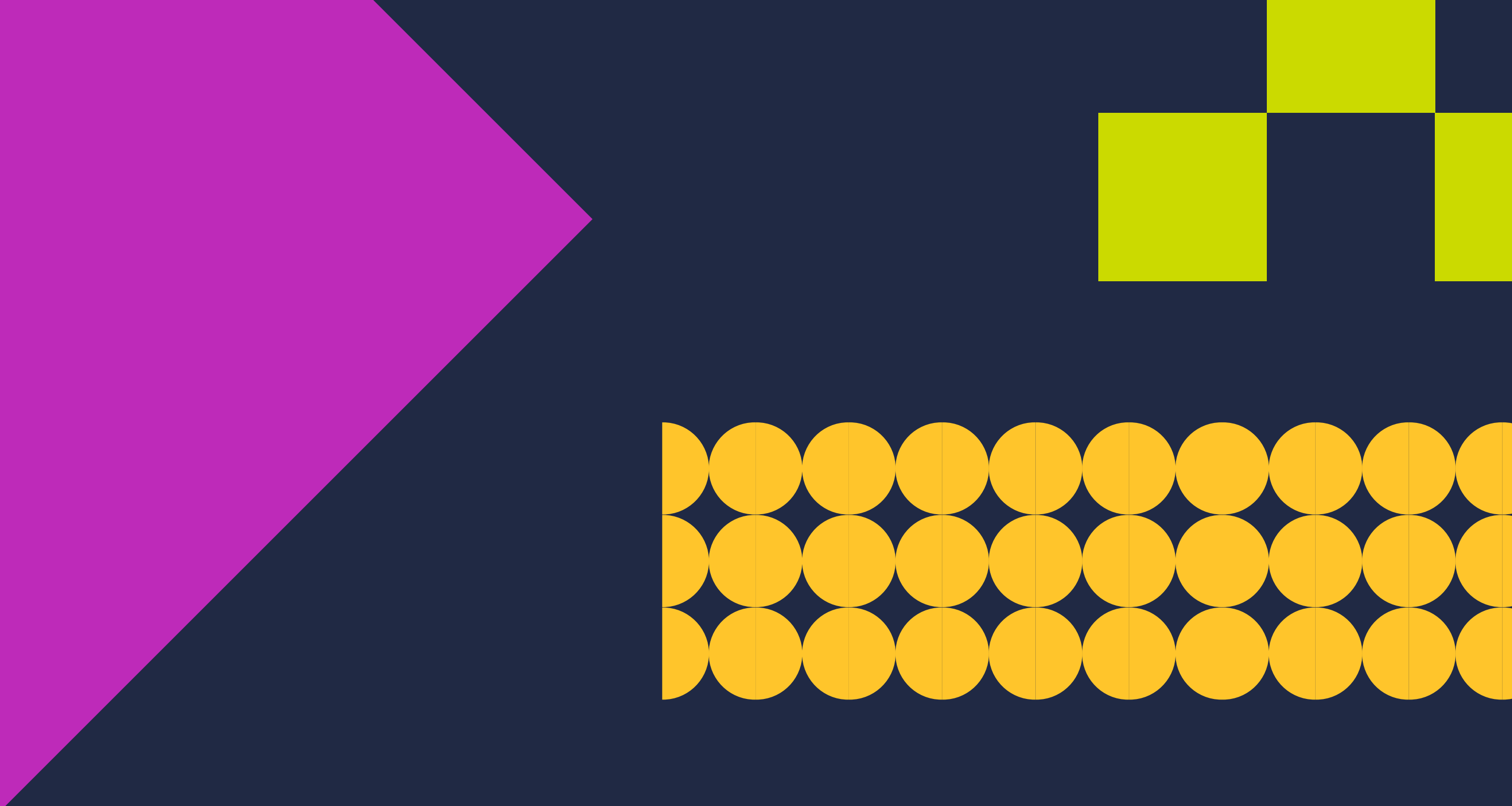
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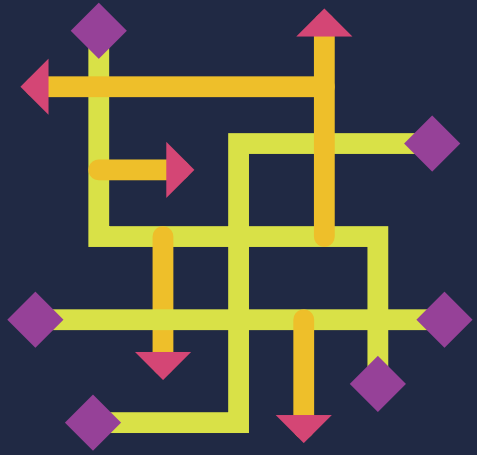


Multiple myeloma has unique characteristics requiring specialized care, dedicated research, and tailored approaches to address its intricacies.



## INCURABLE

Despite significant advancements, multiple myeloma remains an incurable disease<sup>2</sup>



## COMPLEX

Multiple myeloma is highly heterogeneous and requires a myriad of treatment options.<sup>2</sup> These treatments need careful selection, and often combination or sequencing, specific to each patient.<sup>2</sup> This creates complexity for healthcare teams and their patients.<sup>3</sup>



## CONTINUOUS

Multiple myeloma involves cycles of response, remission, and relapse.<sup>2</sup>



## HIGH BURDEN

Multiple myeloma has historically been associated with the lowest health-related quality of life of all blood cancers.<sup>4</sup> Living with multiple myeloma places a substantial physical, psychological, and financial burden on patients and their caregivers.<sup>5-8</sup>





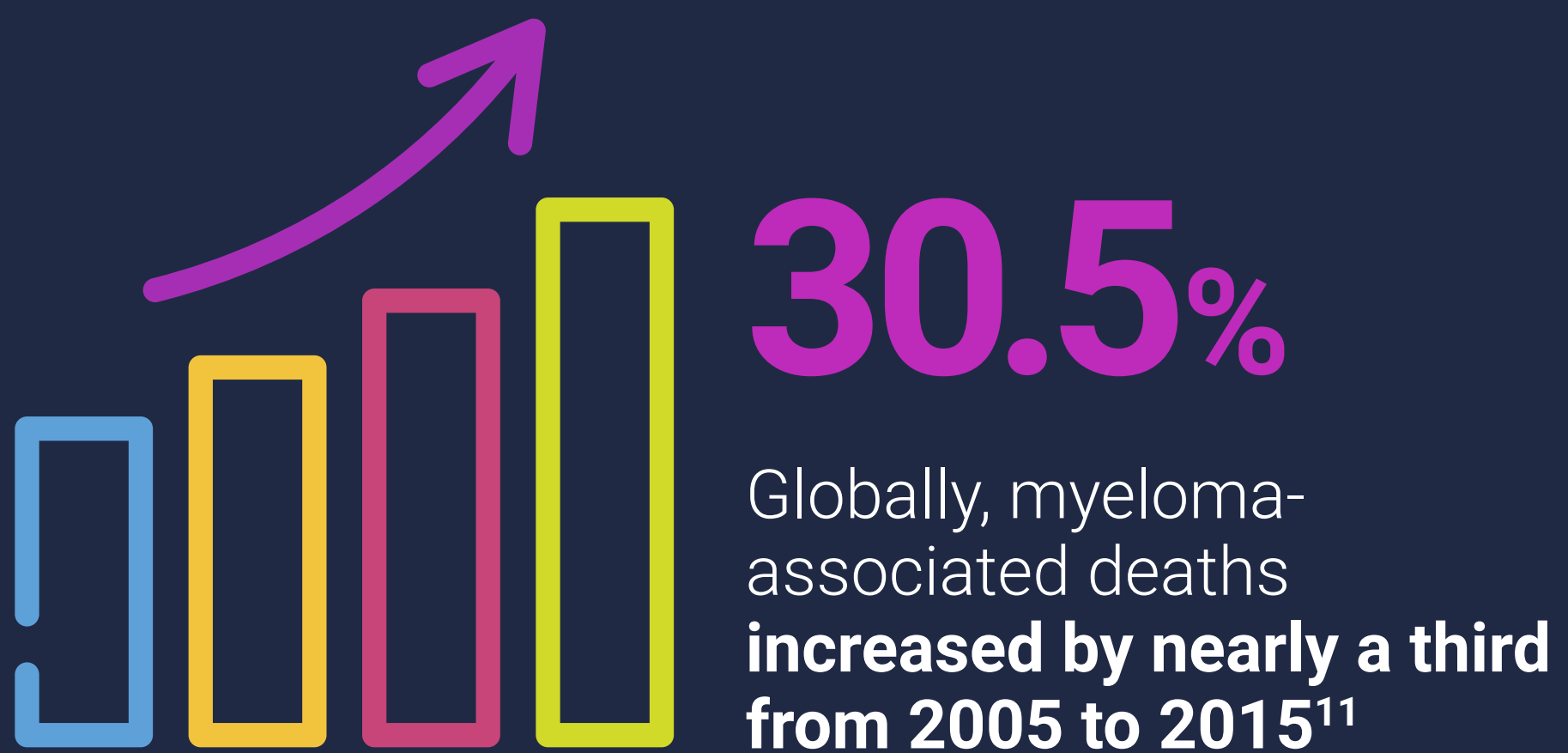
## DISPARATE

Sociodemographic factors such as racial background, access to treatment, insurance coverage, and geographic location significantly influence the ability of practitioners to optimize treatment, leading to multiple myeloma care disparities<sup>9</sup>



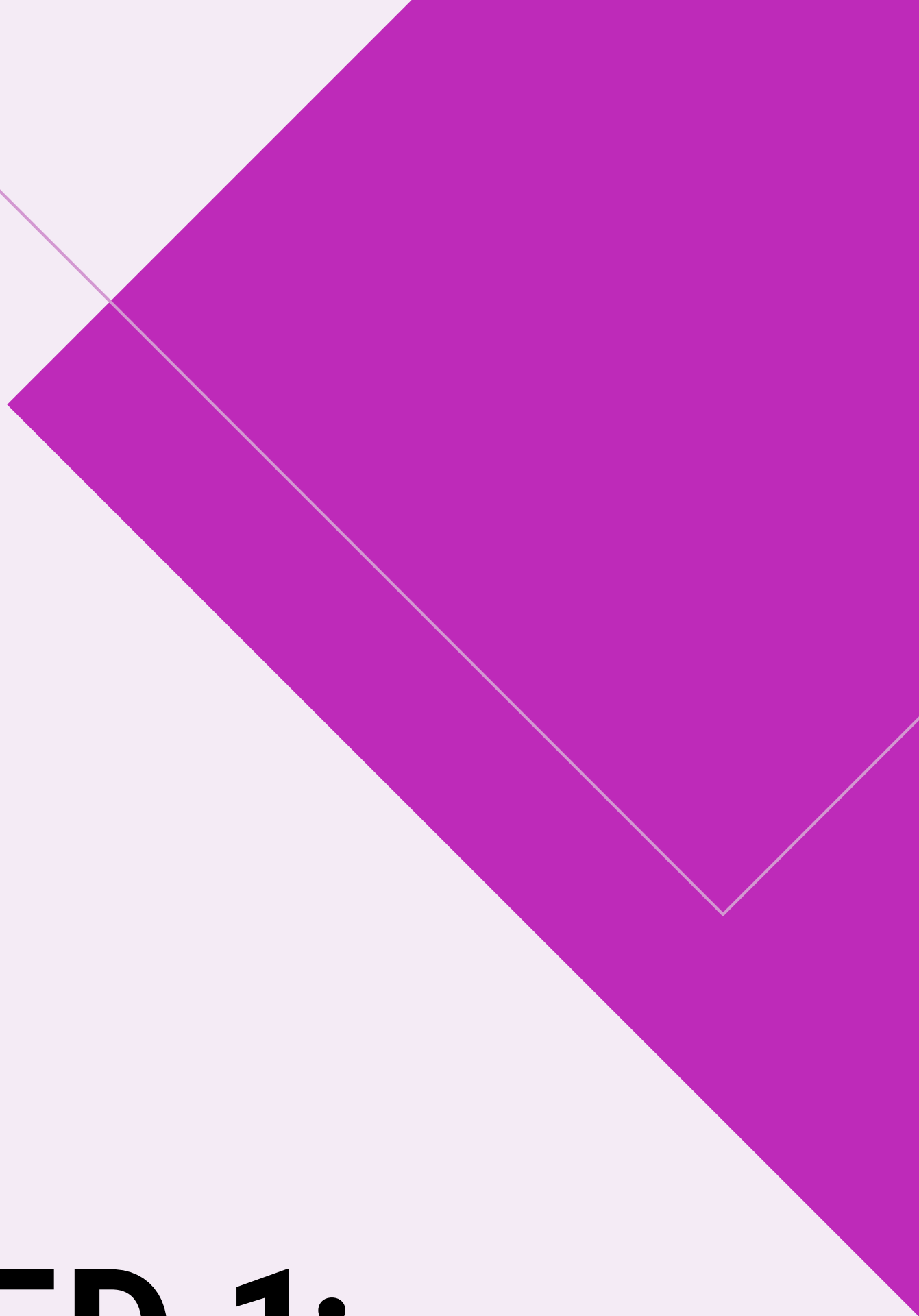
## INCREASING

Incidence rates of multiple myeloma more than doubled between 1999 and 2019.<sup>10</sup> Aging populations may continue to further contribute to this increase.<sup>10</sup>

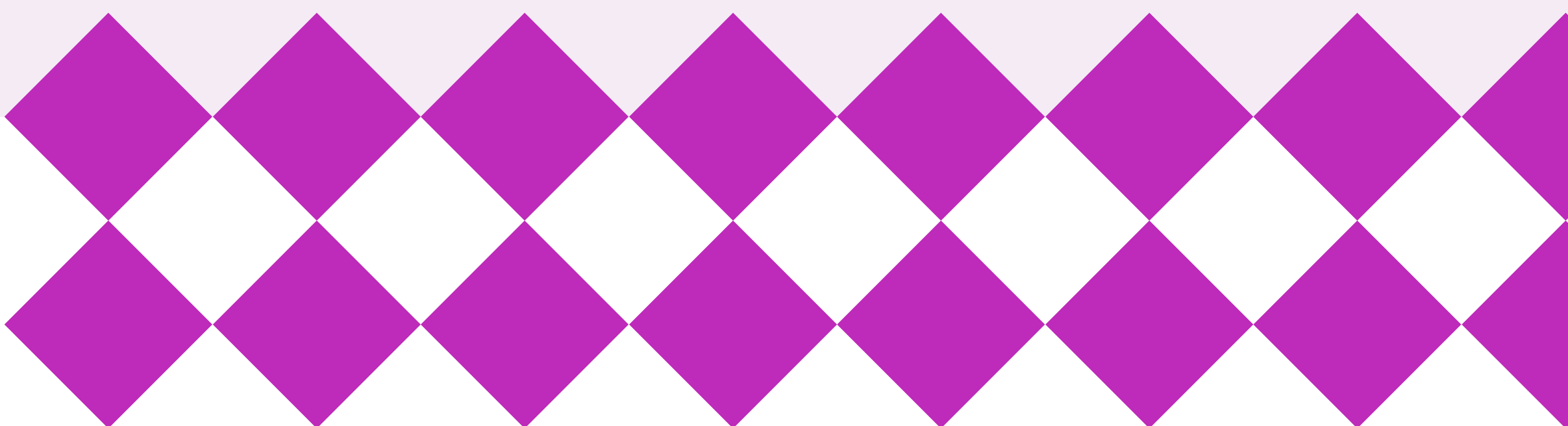


Unfortunately, there still remains a number of unmet needs preventing optimal care from being delivered consistently, globally.

Four key unmet needs have been identified by the Collaboration Council and are covered within this document.



# **UNMET NEED 1: DELAYS IN TIMELY DIAGNOSIS OF MULTIPLE MYELOMA**





# UNMET NEED 1: DELAYS IN TIMELY DIAGNOSIS OF MULTIPLE MYELOMA

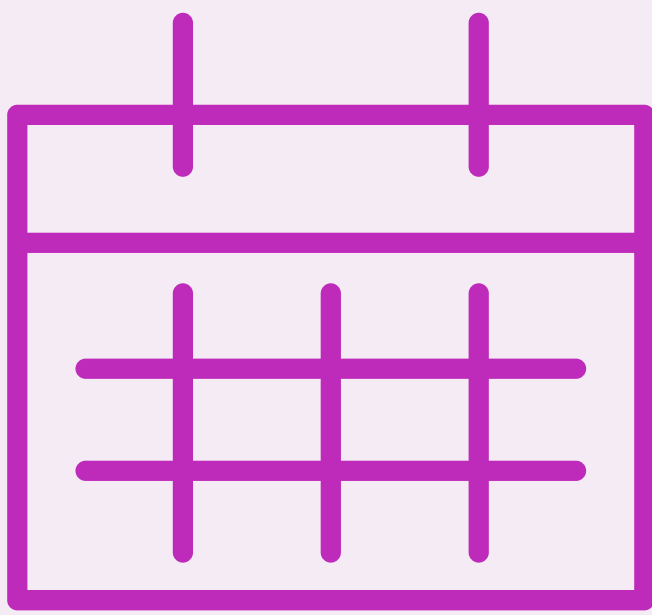
## Delays in diagnosis of patients with multiple myeloma impact both complications and outcomes<sup>12</sup>

Delays in diagnosis of multiple myeloma have been associated with an increased risk of complications, extramedullary disease, and lower disease-free survival.<sup>12,13</sup> Its non-specific symptoms make multiple myeloma challenging to diagnose, with common comorbidities that may mask its presence and lead to a confounding diagnosis.<sup>14</sup>

Non-myeloma specialists, such as primary care practitioners, general community oncologists and general specialists remain critical to achieving a timely multiple myeloma diagnosis.<sup>15</sup> Most primary care practitioners, however, rarely encounter multiple myeloma in their clinical practice – a general practitioner in the UK will diagnose multiple myeloma on average once every 5 years.<sup>14</sup> Low awareness among primary care practitioners may potentially limit referrals to hematologists.<sup>15</sup>

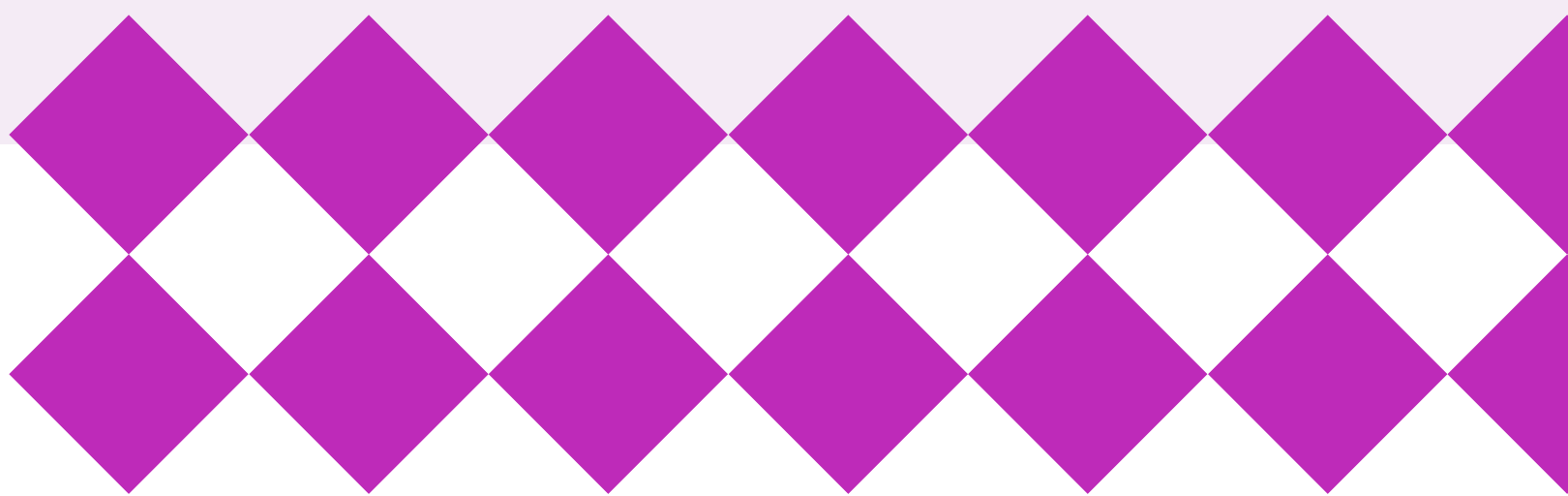


Multiple myeloma has the highest number of patients who receive **more than 3 consultations** prior to a specialist referral of any other reported cancer<sup>16</sup>



In a UK real-world cohort study of 2,626 patients with multiple myeloma, nearly half of all of patients presenting with bone pain **waited approximately 7 months** for a diagnosis<sup>17</sup>

When symptoms and basic lab results might be suggestive of multiple myeloma, extended diagnostics, including multiple protein assays should be conducted to rule out other diagnoses and potentially reduce treatment delays.<sup>18</sup> However, 33% of hematologists reported that limited access to testing can hinder timely diagnosis.<sup>15</sup>



## CALL-TO-ACTION:

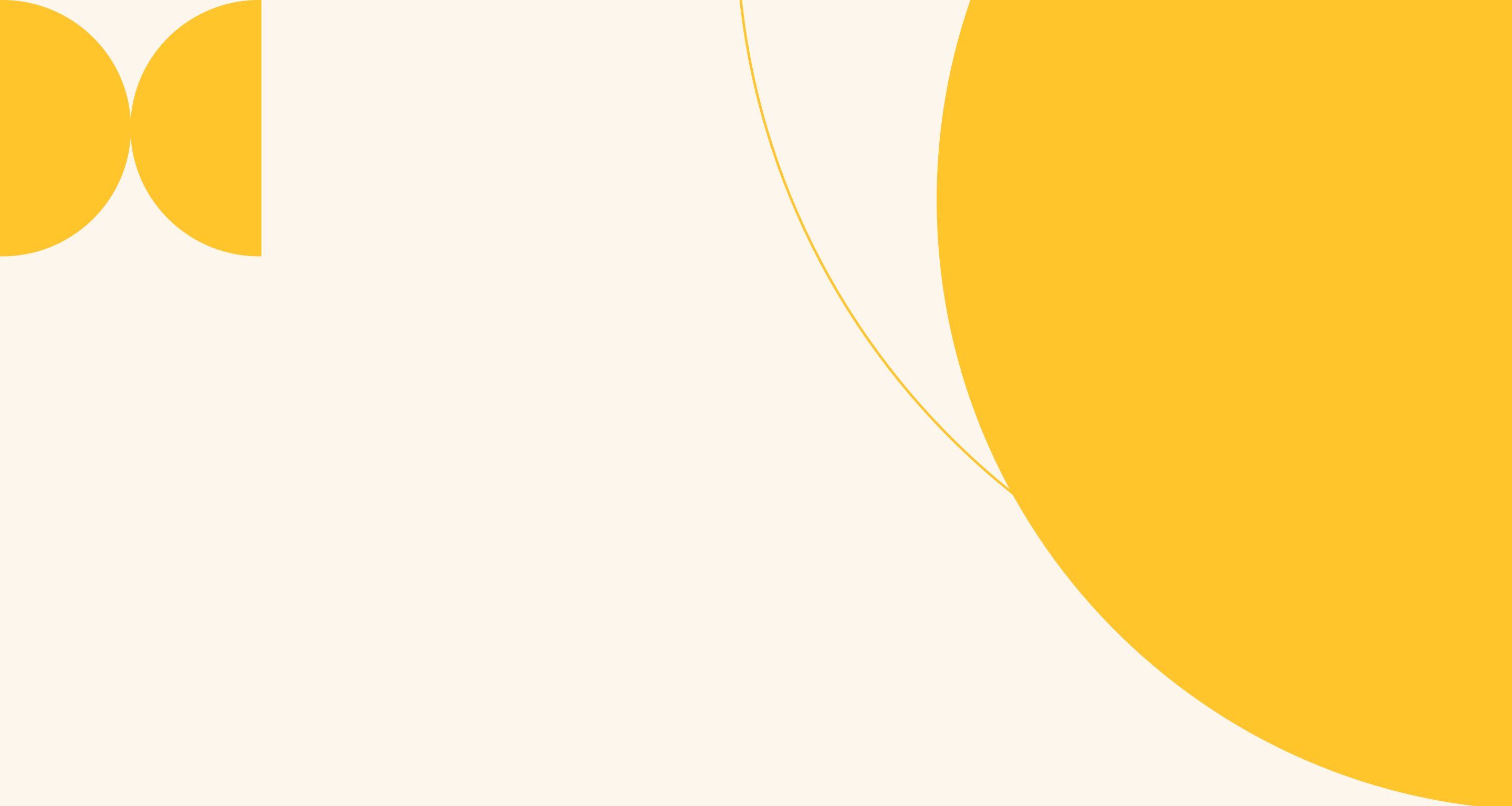


### **Increase multiple myeloma education and awareness to drive earlier diagnosis by:**

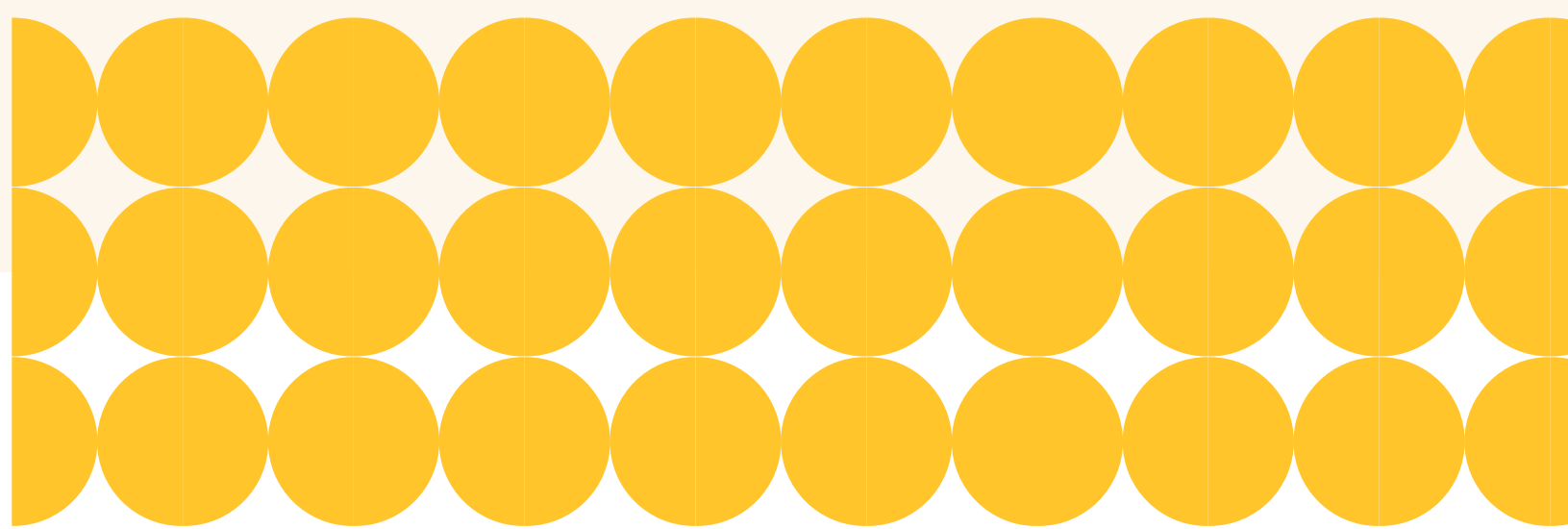
- Developing and leveraging educational resources for non-myeloma specialists
- Advancing the development and awareness of risk stratification tools
- Increasing recognition of conditions that can obscure multiple myeloma

### **Improve access to testing and expedite referral to specialists by:**

- Increasing non-myeloma specialist access to the most sensitive multiple myeloma diagnostic testing combinations, and to multiple myeloma specialist intervention through standardized processes at referring centers
- Creating localized academic support and outreach programs to community networks



# **UNMET NEED 2: COMPLEX TREATMENT DECISION-MAKING IN MULTIPLE MYELOMA**

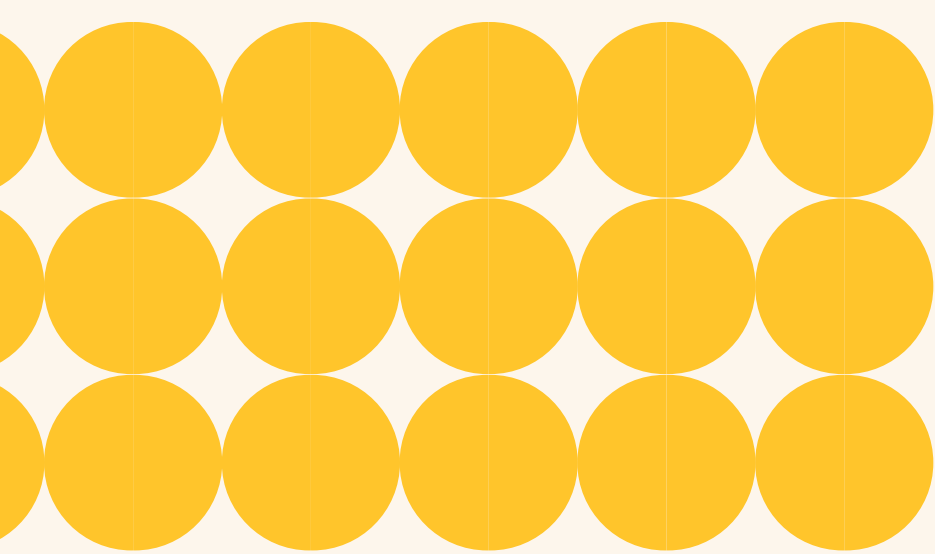


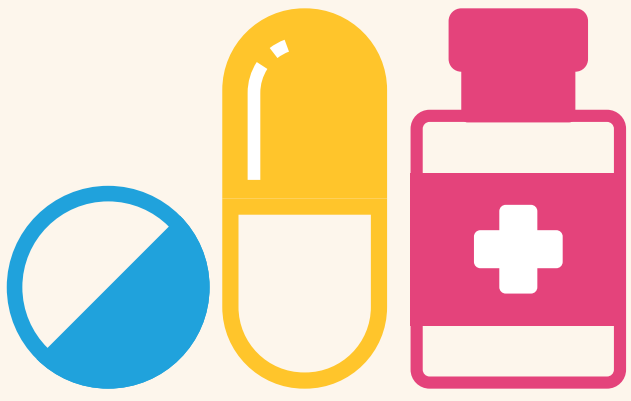
# UNMET NEED 2: COMPLEX TREATMENT DECISION-MAKING IN MULTIPLE MYELOMA

**The complex myeloma treatment paradigm can impact optimal treatment decision-making<sup>19,20</sup>**

The treatment landscape for patients with multiple myeloma is broadening, and outcomes are improving.<sup>19,20</sup> However, the increase in available treatment options, and the highly heterogeneous patient population has led to significant complexity, which is proving challenging for practitioners to navigate.<sup>3,19,21</sup>

This is particularly prevalent for patients with relapsed/refractory multiple myeloma (RRMM) due to the lack of a clear treatment algorithm.<sup>22</sup>





In one real-world study of patients with triple-class exposed RRMM, **92 combinations** of standard of care treatments were prescribed<sup>23</sup>



The largest study on predictive biomarkers to date identified **63 driver genes** that recurrently mutate, initiating and/or driving disease progression<sup>24</sup>

The introduction of more effective therapies necessitates improved metrics, like minimal residual disease (MRD), to assess depth of response.<sup>20</sup> Despite ongoing research,<sup>21</sup> the use of MRD negativity in clinical practice remains unclear.<sup>22,26</sup>

The complexity of multiple myeloma care is compounded by the risk of infection, driven by both the disease's immunodeficiency and cumulative treatments,<sup>27</sup> necessitating better infection risk mitigation.

Access to therapies is hindered by local reimbursement policies and lack of access to clinical trials, contributing to global disparities in care.<sup>28-31</sup>



## CALL-TO-ACTION:



### **Enhance the understanding of individualized treatment response by:**

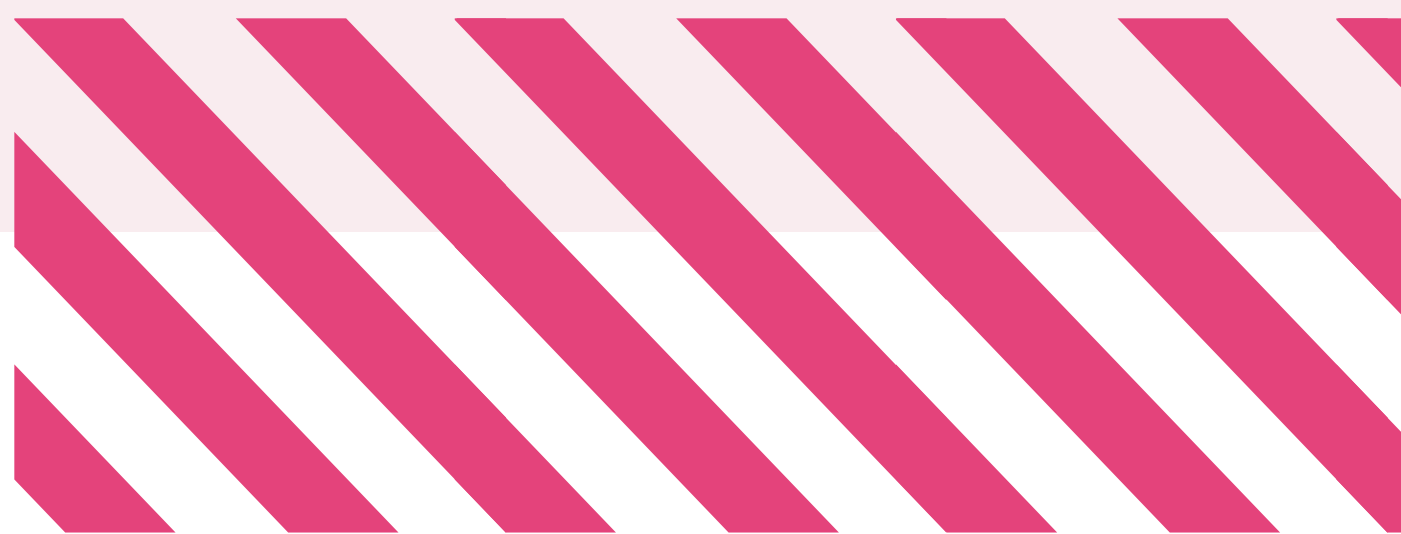
- Ensuring clinical studies are powered to enable effective subgroup analysis
- Redefining treatment algorithms by incorporating novel therapies
- Developing strategies to improve global access to advanced treatments
- Ensuring infection risk reduction guidelines are adopted
- Investing in innovative therapies to mitigate the impact of infection

### **Drive consensus on the utilization of MRD and other surrogate measures by:**

- Harmonizing the integration of MRD into clinical trial design
- Ensuring global access to MRD testing
- Educating HCPs on the role of MRD in clinical practice for effective patient communication
- Exploring existing and novel biomarkers to enhance prognostic capability and inform treatment decisions



# **UNMET NEED 3: LIMITED APPLICABILITY AND DIVERSITY OF CLINICAL TRIALS**



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Multiple myeloma trials often do not reflect real-world populations, limiting application of results in clinical practice<sup>32</sup>

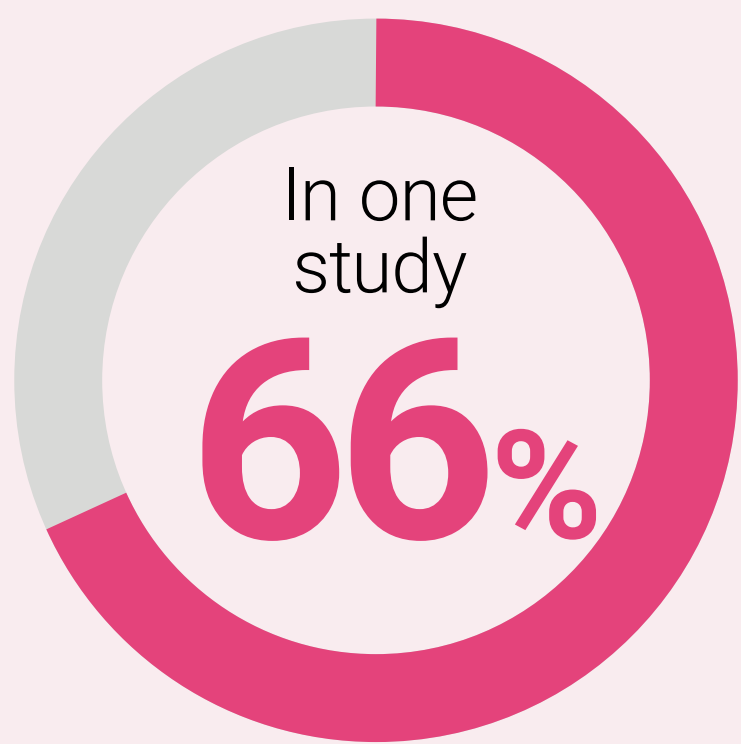
The inclusion criteria for clinical trials are often too narrow to incorporate a significant proportion of patients with multiple myeloma.<sup>32,33</sup> This includes patients with RRMM, who are even less likely to qualify for trial inclusion and have a 50% increased risk of mortality compared with those who are eligible for trial inclusion.<sup>3</sup>



Approximately **40%** of all real-world patients with multiple myeloma **do not meet the inclusion criteria** for Phase 3 trials<sup>32</sup>



of real-world patients with RRMM **fail to meet clinical trial inclusion criteria**<sup>3</sup>



of real-world patients with RRMM **started treatment at a lower dose** than suggested in clinical trials<sup>34</sup>

This may lead to clinical trial data that do not accurately reflect the broader real-world multiple myeloma population. This is evident in instances where treatment tolerability is lower in real-world patients compared to those administered in clinical trials.<sup>34,35</sup>

Limited local availability of appropriate trial resources in middle- and low-income countries, as well as suboptimal infrastructure and staffing in smaller and rural institutions, can further limit trial inclusion and representation of patients in multiple myeloma trials.<sup>36,37</sup> This unfortunately results in the underrepresentation of these patients within clinical trials.

## CALL-TO-ACTION:



### **Reinforce access, diversity, and equality across clinical trial populations by:**

- Establishing a clinical trial infrastructure with regulatory standards that supports the expansion of trials into underserved communities
- Encouraging collaboration to help countries educate HCPs, prioritize available resources, and improve trial access
- Educating on trial availability, objectives, and execution, enabling discussion between healthcare professionals (HCPs) and patients
- Increasing awareness of under-represented groups with clear metrics for policymakers to address global disparities in care

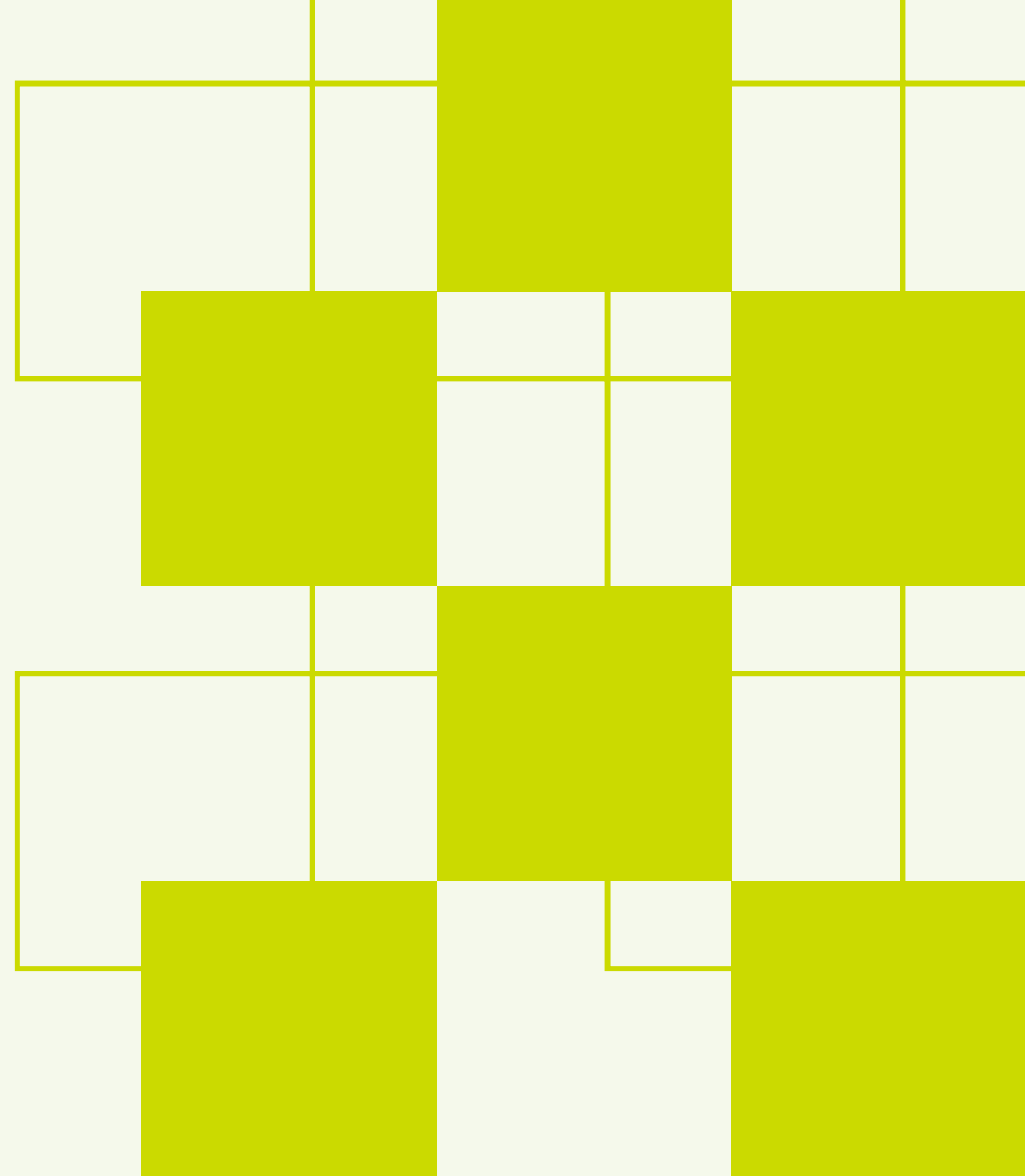
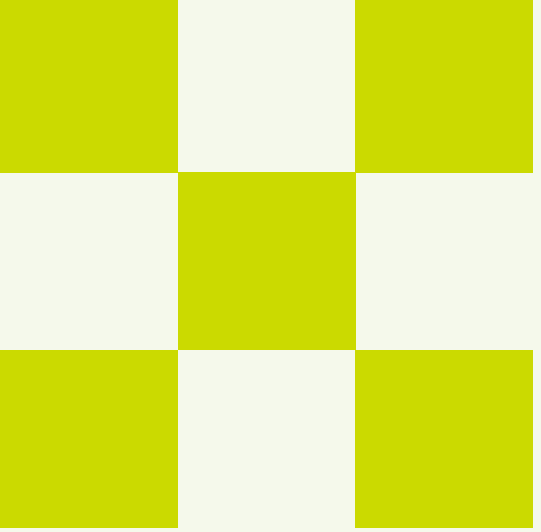
### **Increase the prioritization of patient experience-related outcomes by:**

- Integrating quality-of-life assessments as essential clinical trial endpoints
- Routinely incorporating patient insights in study design
- Generating real-world quality-of-life data alongside clinical trial data

## Improve applicability and relevance of clinical trial data in clinical practice by:

- Expanding inclusion and exclusion criteria and designing smaller studies for specific patient sub-populations
- Collecting real-world evidence across diverse geographies and socioeconomic populations to inform individualized treatment strategies





# **UNMET NEED 4: INCONSISTENT HOLISTIC MANAGEMENT OF MULTIPLE MYELOMA**



# **UNMET NEED 4: INCONSISTENT HOLISTIC MANAGEMENT OF MULTIPLE MYELOMA**

**Current care models may not effectively address the broader needs of patients consistently, including psychosocial support and shared decision-making<sup>5</sup>**

Survival outcomes for patients with multiple myeloma are improving,<sup>20</sup> and focus on patient quality of life is growing.<sup>38,39</sup> However, a need to alleviate the impact of the life-long burden of the disease for patients and non-professional caregivers remains. This may be achieved by utilizing a holistic care approach with multidisciplinary team (MDT) input.<sup>6,40,41</sup>

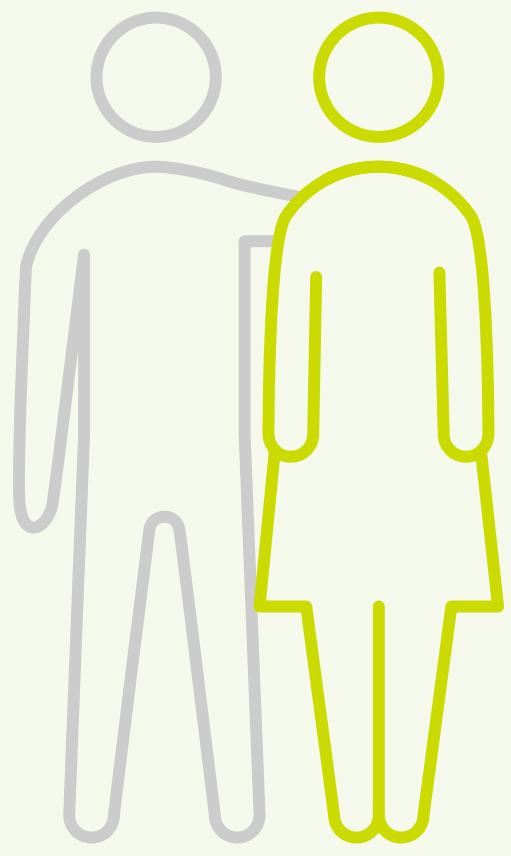
MDTs are tailored to patient needs, combining the unique abilities of a variety of specialists.<sup>42</sup>

MDTs offer an opportunity to improve patient experience and associated outcomes.<sup>42</sup>

However, access to MDTs can be limited by socioeconomic status and geographical location, demonstrating inconsistent adoption of MDT care.<sup>43</sup>



There is a need for holistic care models, in addition to innovative therapies, to support patients and caregivers psychologically, socially, physically, spiritually, and financially.<sup>40</sup>



A study of patients with newly diagnosed multiple myeloma (NDMM) in Western Europe found that **90% of patients stopped leisure activities** such as spending time with family and friends 1 year after diagnosis<sup>6</sup>



A Western European study found **97% of patients with NDMM rely on caregivers to provide holistic care**<sup>6</sup>

**48% of multiple myeloma caregivers were diagnosed with stress, anxiety, or depression in the 1 year following diagnosis of the patient for whom they were providing care**<sup>6</sup>

Improving HCP-patient communication can strengthen the practice of shared decision-making (SDM),<sup>†</sup> which is essential to ensure both patient and doctor are aware and conscious of the various factors to be considered when creating an individual treatment strategy.<sup>44</sup>

<sup>†</sup> Shared decision-making (SDM) describes a process in which open and honest communication between patients and practitioners enables treatment choices which simultaneously optimize clinical outcomes and honor individual values and preferences.<sup>44</sup>

## CALL-TO-ACTION:



### **Ensure awareness of patient needs along the multiple myeloma journey by:**

- Guiding patients to specialized healthcare providers through nurse navigators, a global portal, country-specific helplines, and patient group networks
- Developing standardized tools for electronic medical records to consistently assess evolving patient needs

### **Drive consistent integration and access to MDTs at multiple myeloma care centers by:**

- Creating guidance for the integration of MDTs, using technology for remote access
- Promoting initiatives that emphasize MDT care, continuity, and collaboration within the myeloma community

### **Establish the value of SDM in clinical practice by:**

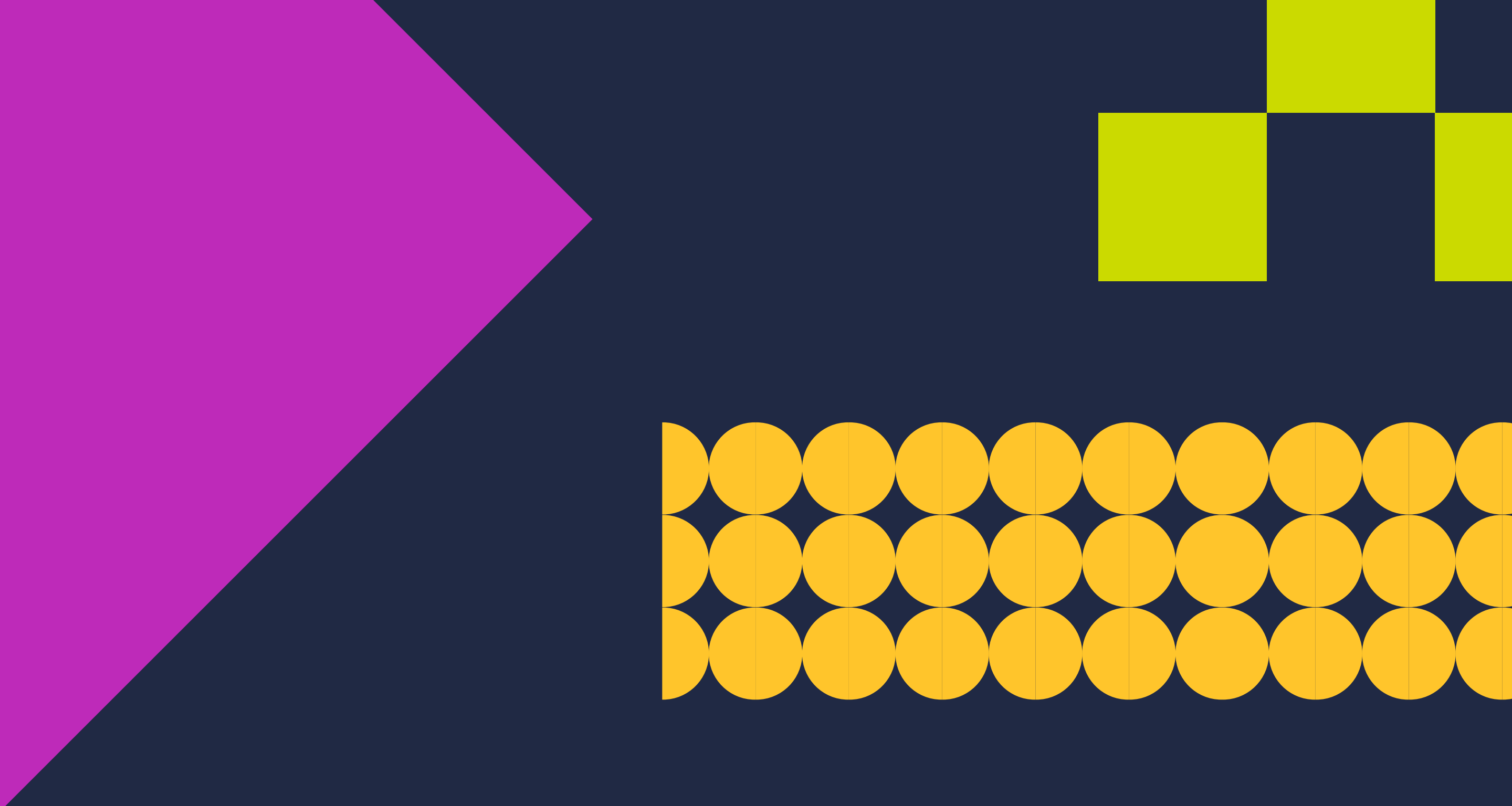
- Raising awareness of SDM
- Conducting real-world studies on the applicability of SDM to multiple myeloma
- Developing SDM tools, training programs, and communication aids to enhance HCP-patient relationships

**The Collaboration Council is committed to encouraging and accelerating progress in multiple myeloma, by actively identifying unmet needs and inspiring innovative solutions to address them. Through multidisciplinary engagement across the spectrum of care, the global multiple myeloma community can start to imagine a future where cure might be possible for many more patients living with multiple myeloma.**

**Together we can shape the future of myeloma care.**

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This document is a  
concise summary of the  
Multiple Myeloma Call-to-  
Action. For the complete  
report, please click here:

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